



# SAFETY DATA SHEET

Revision date: 15-May-2018

Version: 2.0

Page 1 of 10

## 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

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

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

**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**

## SAFETY DATA SHEET

Material Name: RETACRIT (epoetin-alfa-epbx)  
Revision date: 15-May-2018

Page 2 of 10  
Version: 2.0

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Calcium chloride USP	10035-04-8	Not Listed	Eye Irrit. 2 (H319)	<1.0
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Glutamic acid	56-86-0	200-293-7	Not Listed	*
Leucine	61-90-5	200-522-0	Not Listed	*
L-Isoleucine	73-32-5	200-798-2	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Glycine	56-40-6	200-272-2	Not Listed	*
Phenylalanine	63-91-2	200-568-1	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Polysorbate 20	9005-64-5	Not Listed	Not Listed	*
L-Threonine	72-19-5	200-774-1	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Epoetin alfa	113427-24-0	Not Listed	Not Listed	*
Sodium Phosphate Monobasic, Monohydrate	10049-21-5	Not Listed	Not Listed	*

**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

## SAFETY DATA SHEET

Material Name: RETACRIT (epoetin-alfa-epbx)  
Revision date: 15-May-2018

Page 3 of 10  
Version: 2.0

### 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/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

**Glutamic acid**

Latvia OEL - TWA 10 mg/m<sup>3</sup>

**Leucine**

## SAFETY DATA SHEET

Material Name: RETACRIT (epoetin-alfa-epbx)  
Revision date: 15-May-2018

Page 4 of 10  
Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA	5 mg/m <sup>3</sup>
<b>L-Threonine</b>	
Latvia OEL - TWA	2 mg/m <sup>3</sup>
<b>L-Isoleucine</b>	
Latvia OEL - TWA	5 mg/m <sup>3</sup>
<b>Glycine</b>	
Latvia OEL - TWA	5 mg/m <sup>3</sup>
<b>Phenylalanine</b>	
Latvia OEL - TWA	5 mg/m <sup>3</sup>

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.

#### Calcium chloride USP

**Pfizer Occupational Exposure Band (OEB):** OEB 2 - Severe Eye Irritant (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, provide additional precautions to protect from skin contact)

#### Sodium chloride

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### Sodium phosphate, dibasic

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### Epoetin alfa

**Pfizer Occupational Exposure Band (OEB):** B-OEB 5 (control exposure to <10 µg/day)

#### 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.)

## SAFETY DATA SHEET

Material Name: RETACRIT (epoetin-alfa-epbx)  
Revision date: 15-May-2018

Page 5 of 10  
Version: 2.0

### 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

<b>Physical State:</b>	Liquid	<b>Color:</b>	Clear, colorless
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	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

## SAFETY DATA SHEET

Material Name: RETACRIT (epoetin-alfa-epbx)  
Revision date: 15-May-2018

Page 6 of 10  
Version: 2.0

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:	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	1940mg/kg

##### Glycine

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

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

##### Sodium chloride

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

##### Calcium chloride USP

Eye Irritation	Rabbit	Moderate
----------------	--------	----------

## SAFETY DATA SHEET

Material Name: RETACRIT (epoetin-alfa-epbx)  
Revision date: 15-May-2018

Page 7 of 10  
Version: 2.0

### 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.

## SAFETY DATA SHEET

Material Name: RETACRIT (epoetin-alfa-epbx)  
Revision date: 15-May-2018

Page 8 of 10  
Version: 2.0

### 15. REGULATORY INFORMATION

#### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### Calcium chloride USP

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

##### Sodium chloride

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	231-598-3

##### Polysorbate 20

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	Not Listed

##### Glutamic acid

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	200-293-7

##### Leucine

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	200-522-0

##### L-Threonine

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	200-774-1

##### L-Isoleucine

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed



## SAFETY DATA SHEET

Material Name: RETACRIT (epoetin-alfa-epbx)  
Revision date: 15-May-2018

Page 9 of 10  
Version: 2.0

### 15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-798-2
<b>Sodium phosphate, dibasic</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7
<b>Water for Injection</b>	
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
<b>Glycine</b>	
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	200-272-2
<b>Epoetin alfa</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Sodium Phosphate Monobasic, Monohydrate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Phenylalanine</b>	
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	200-568-1

### 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

## SAFETY DATA SHEET

**Material Name:** RETACRIT (epoetin-alfa-epbx)  
**Revision date:** 15-May-2018

**Page 10 of 10**  
**Version: 2.0**

---

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  
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**