SAFETY DATA SHEET

# PROCRIT

| Version | Revision Date: | SDS Number: | Date of last issue: 2015/03/21 |
|---|---|---|---|
| 1.33 | 2015/04/21 | 100000010006 | Date of first issue: 2013/12/24 |

## SECTION 1. IDENTIFICATION

Product name : PROCRIT
Substance name : EPREX / PROCRIT
epoetin alfa

**Manufacturer or supplier's details**

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560
US

Telephone : (609) 730-2000

**Emergency telephone number : +32 14 60 24 44**

E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Finished Pharmaceutical Product
Large Molecule Pharmaceutical intended for medical use
Pharmacotherapeutic group: Antianemic preparations
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is not exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

## SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification**

Reproductive toxicity : Category 2

**GHS Label element**

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Hazard pictograms :

Signal word : Warning

Hazard statements : H361 Suspected of damaging fertility or the unborn child.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P281 Use personal protective equipment as required.
**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
**Storage:**
P405 Store locked up.
**Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic respons. May cause sensitization of susceptible persons.
Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidently leaking, broken or crushed.
The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
58.96 %

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Hazardous components**

| Chemical Name | CAS-No. | Concentration (%) |
|---|---|---|
| Epoetin alfa | 113427-24-0 | >= 1 - < 5 |

## SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off immediately with plenty of water.
If symptoms persist, call a physician.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).
Call a physician immediately.

Most important symptoms and effects, both acute and : nausea
Vomiting

| | | |
|---|---|---|
| delayed | | Itching<br>headache<br>Cough<br>hypertension<br>Rash<br>Swelling of tissue<br>Pain |
| Notes to physician | : | Treat symptomatically.<br>Consult the patient packaging insert for more information about this Finished Pharmaceutical Product. |

## SECTION 5. FIREFIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Specific hazards during firefighting | : | No information available. |
| Further information | : | No information available. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.<br>Evacuate personnel to safe areas. |
| Environmental precautions | : | Should not be released into the environment.<br>Do not flush into surface water or sanitary sewer system. |
| Methods and materials for containment and cleaning up | : | Clean up with soap and water or a solution containing at least 10% sodium hypochlorite (1 part sodium hypochlorite ("Bleach"), mixed with 9 parts water) is recommended for cleaning of surfaces and equipment.<br>Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".<br>Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers.<br>Small spills: Gently cover the spill with an absorbent towel or pad. |

## SECTION 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| Advice on protection against fire and explosion | : | No data available |

| | | |
|---|---|---|
| Advice on safe handling | : | To avoid thermal decomposition, do not overheat.<br>For personal protection see section 8.<br>Avoid inhalation, ingestion and contact with skin and eyes.<br>Do not break, crush or spill this Finished Pharmaceutical Product. |
| Conditions for safe storage | : | To maintain product quality, do not store in heat or direct sunlight.<br>Store in original container.<br>Keep containers tightly closed in a dry, cool and well-ventilated place.<br>Keep away from heat and sources of ignition. |
| Recommended storage temperature | : | 2 - 8 °C |

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| Epoetin alfa | 113427-24-0 | PBOEL-HHC | 3 A | J&J OEL/PBOEL HHC |
| | Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3A. This means that the OEL is estimated to be from 5 to 20 µg/m3 | | | |

**Engineering measures** : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

**Personal protective equipment**

| | | |
|---|---|---|
| Respiratory protection | : | No personal respiratory protective equipment normally required.<br>Engineering controls should always be the primary method of controlling exposures.<br>If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present. |
| Hand protection | | |
| Remarks | : | No special precautions required. |
| Eye protection | : | No special precautions required. |

| | | |
|---|---|---|
| Skin and body protection | : | No special precautions required. |
| Protective measures | : | The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary. |
| Hygiene measures | : | Handle in accordance with good industrial hygiene and safety practice. |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Appearance | : | Vial |
| Colour | : | colourless |
| pH | : | 5.8 - 6.4 |
| Melting point/range | : | -0.4 °C |
| Boiling point/boiling range | : | 100 °C<br>(1,013 hPa) |

## SECTION 10. STABILITY AND REACTIVITY

| | | |
|---|---|---|
| Reactivity | : | None reasonably foreseeable. |
| Chemical stability | : | Stable under recommended storage conditions. |
| Possibility of hazardous reactions | : | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | : | To avoid thermal decomposition, do not overheat.<br>Exposure to light. |
| Incompatible materials | : | None known. |
| Hazardous decomposition products | : | None known. |

## SECTION 11. TOXICOLOGICAL INFORMATION

**Acute toxicity**

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: 4,931 mg/kg<br>Method: Calculation method |

**Components:**

**Epoetin alfa**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 20000 UI/kg |

Remarks: No adverse effect has been observed in acute toxicity tests.
No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): > 20000 UI/kg
Application Route: intravenous injection

LD50 (dogs): > 20000 UI/kg
Application Route: injection made in the posterior thigh muscle

**Skin corrosion/irritation**

No data available

**Serious eye damage/eye irritation**

No data available

**Respiratory or skin sensitisation**

No data available

**Germ cell mutagenicity**

**Components:**

**Epoetin alfa**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Species: Human lymphocytes
Remarks: In vitro tests did not show mutagenic effects

: Species: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Remarks: In vitro tests did not show mutagenic effects

:

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Cell type: Bone marrow
Result: In vivo tests did not show any chromosomal changes.

**Carcinogenicity**

**IARC** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**NTP** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

**Components:**

**Epoetin alfa**

| | | |
|---|---|---|
| Effects on fertility | : | Species: Rat<br>Dose: 100 UI/kg/day<br><br>Remarks: Adverse effects on sexual function and fertility. |
| Effects on foetal development | : | Species: Rat, females<br>Application Route: intravenous injection<br>Dose: 500 mg/kg/day<br>Remarks: Did not show teratogenic effects in animal experiments.<br>Species: Rabbit<br>Application Route: intravenous injection<br>Dose: 500 mg/kg/day<br>Remarks: Did not show teratogenic effects in animal experiments.<br>Species: Rat, females<br>Application Route: intravenous injection<br>Dose: 500 UI/kg/day<br>Remarks: Did show teratogenic effects in animal experiments. |
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on development, based on animal experiments., Fertility classification not possible from current data. |
| Teratogenicity - Assessment | : | Potential embryo-foetal toxicity and teratogenicity., Limited evidence of adverse effects on development in animal studies and/ or human studies. |

**STOT - single exposure**

No data available

**STOT - repeated exposure**

**Components:**

**Epoetin alfa**

Target Organs: Blood, Central nervous system, Cardio-vascular system, Immune system

**Repeated dose toxicity**

No data available

**Aspiration toxicity**

No data available

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

## SECTION 14. TRANSPORT INFORMATION

**International transport regulations**

**ADR**
Not dangerous goods

**RID**
Not dangerous goods

**DOT**
Not dangerous goods

**IATA**
Not dangerous goods

**IMDG**
Not dangerous goods

## SECTION 15. REGULATORY INFORMATION

**EPCRA - Emergency Planning and Community Right-to-Know Act**

**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

| | | |
|---|---|---|
| Glycine | 56-40-6 | 33.89 % |

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

| | | |
|---|---|---|
| SODIUM PHOSPHATE DIBASIC | 7558-79-4 | 15.18 % |

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**Massachusetts Right To Know**

| | | |
|---|---|---|
| SODIUM PHOSPHATE DIBASIC | 7558-79-4 | 10 - 20 % |

**Pennsylvania Right To Know**

| | | |
|---|---|---|
| Glycine | 56-40-6 | 30 - 50 % |
| Sodium chloride (NaCl) | 7647-14-5 | 20 - 30 % |
| SODIUM PHOSPHATE DIBASIC | 7558-79-4 | 10 - 20 % |
| | Not Assigned | 5 - 10 % |
| water | 7732-18-5 | 5 - 10 % |
| Epoetin alfa | 113427-24-0 | 1 - 5 % |

**New Jersey Right To Know**

| | | |
|---|---|---|
| Glycine | 56-40-6 | 30 - 50 % |
| Sodium chloride (NaCl) | 7647-14-5 | 20 - 30 % |
| SODIUM PHOSPHATE DIBASIC | 7558-79-4 | 10 - 20 % |
| | Not Assigned | 5 - 10 % |
| water | 7732-18-5 | 5 - 10 % |

**California Prop 65** This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other re-

productive harm.

**Other regulations** : According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.
For professional users only.

**The components of this product are reported in the following inventories:**

REACH : Not in compliance with the inventory

: Sodium chloride (NaCl)

: Glycine

: SODIUM PHOSPHATE DIBASIC

: water

:

:

: Epoetin alfa

CH INV : The formulation contains substances listed on the Swiss Inventory

: Sodium chloride (NaCl)

: Glycine

: SODIUM PHOSPHATE DIBASIC

: water

:

:

: Epoetin alfa

TSCA : Not On TSCA Inventory

: Epoetin alfa

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

: Epoetin alfa

AICS : Not in compliance with the inventory

| | | |
|---|---|---|
| | : | Epoetin alfa |
| NZIoC | : | Not in compliance with the inventory |
| | : | Epoetin alfa |
| ENCS | : | Not in compliance with the inventory |
| | : | water |
| | : | Epoetin alfa |
| ISHL | : | Not in compliance with the inventory |
| | : | water |
| | : | Epoetin alfa |
| KECI | : | Not in compliance with the inventory |
| | : | Epoetin alfa |
| PICCS | : | Not in compliance with the inventory |
| | : | Epoetin alfa |
| IECSC | : | Not in compliance with the inventory |
| | : | Epoetin alfa |

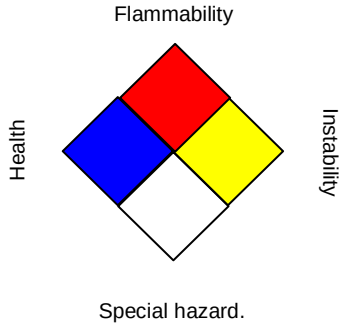
**Inventories**

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

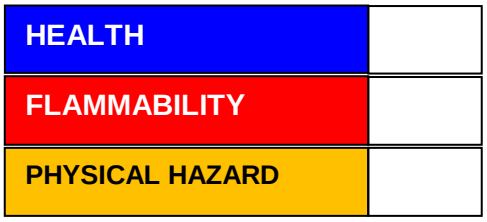
## SECTION 16. OTHER INFORMATION

### Further information

**NFPA:**




**HMIS III:**




0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 2015/04/21

### Date and Number Formats

This document uses the following notation for printing dates and numbers:

| | | | |
|---|---|---|---|
| **Date:** | Dec 31th, 2012 | as | 2012/12/31 |
| **Numbers:** | 123456,78 | as | 1,234,567.89 |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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