

PROCRIT

Version	Revision Date:	SDS Number:	Date of last issue:
1.88	2018/05/19	100000010006	2017/09/21
			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 Research & Development, LLC

Address : 1400 McKean Rd
 Spring House, PA 19477
 US

Telephone : (215) 628-5707
 E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-527-3887

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 elements

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

Hazard pictograms :



Signal word : Warning

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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 response. May cause sensitization of susceptible personse.
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 accidentally 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.

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Most important symptoms and effects, both acute and delayed : nausea
Vomiting
Itching
headache
Cough
hypertension
Rash
Swelling of tissue
Pain

Notes to physician : Treat symptomatically.
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 fire-fighting : 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.
Evacuate personnel to safe areas.

Environmental precautions : Should not be released into the environment.
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.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers.
Small spills: Gently cover the spill with an absorbent towel or pad.

SECTION 7. HANDLING AND STORAGE

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- Advice on protection against fire and explosion : No data available
- Advice on safe handling : To avoid thermal decomposition, do not overheat. Avoid inhalation, ingestion and contact with skin and eyes. Do not break, crush or spill this Finished Pharmaceutical Product. Use personal protective equipment as required.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. 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/m ³				

- 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. Engineering controls should always be the primary method of controlling exposures. 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.

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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 (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. 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 Method: Calculation method
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Components:

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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 on OSHA's list of regulated carcinogens.

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:**

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Epoetin alfa

Effects on fertility

:
Species: Rat
Dose: 100 UI/kg/day

Remarks: Adverse effects on sexual function and fertility.

Effects on foetal development

: Species: Rat, females
Application Route: intravenous injection
Dose: 500 mg/kg/day
Remarks: Did not show teratogenic effects in animal experiments.

Species: Rabbit

Application Route: intravenous injection
Dose: 500 mg/kg/day

Remarks: Did not show teratogenic effects in animal experiments.

Species: Rat, females

Application Route: intravenous injection
Dose: 500 UI/kg/day

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

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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 regula-
tions.

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

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

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SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act**

SARA 302 : This material does not contain any components with a section 302 EHS TPQ.

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 112 (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 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Glycine	56-40-6	33.89 %
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Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

SODIUM PHOSPHATE DIBASIC	7558-79-4	15.18 %
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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 %
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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations**Massachusetts Right To Know**

SODIUM PHOSPHATE DIBASIC	7558-79-4	10 - 20 %
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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 %
	13472-35-0	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 %
	13472-35-0	5 - 10 %
water	7732-18-5	5 - 10 %

SAFETY DATA SHEET



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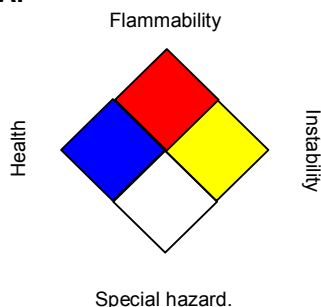
California Prop 65 This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulations : For professional users only.

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

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

Revision Date : 2018/05/19

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 123,456.78

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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