

SAFETY DATA SHEET



PROCRIT

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/03
1.113	2024/12/03	100000010006	Date of first issue: 2013/12/24

SECTION 1. IDENTIFICATION

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

Reference number : JNJ-7472179-AAA

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity : Category 2

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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

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.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity: 58.96 %

Other hazards

Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization in 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 accidentally leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Epoetin alfa	113427-24-0	$\geq 1 - < 5$

Actual concentration is withheld as a trade secret

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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 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 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. Evacuate personnel to safe areas.

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- 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

- 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 : 36 - 46 °F / 2 - 8 °C
- Further information on storage stability : Do not freeze.

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				

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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.
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.

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 : liquid

Colour : colourless

pH : 5.8 - 6.4

Melting point/ range : 31.3 °F / -0.4 °C

Boiling point/boiling range : 212 °F / 100 °C
(1,013 hPa)

SECTION 10. STABILITY AND REACTIVITY

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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

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

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Test system: Human lymphocytes
Remarks: In vitro tests did not show mutagenic effects

Test system: 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:****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.

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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

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

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

No data available

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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 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

SECTION 15. REGULATORY INFORMATION

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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.

US State Regulations

Massachusetts Right To Know

SODIUM PHOSPHATE DIBASIC 7558-79-4

Pennsylvania Right To Know

Glycine 56-40-6
Sodium chloride (NaCl) 7647-14-5
SODIUM PHOSPHATE DIBASIC 7558-79-4
Sodium phosphate, monobasic, dihydrate 13472-35-0

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water 7732-18-5
Epoetin alfa 113427-24-0

New Jersey Right To Know

Glycine 56-40-6
Sodium chloride (NaCl) 7647-14-5
SODIUM PHOSPHATE DIBASIC 7558-79-4
Sodium phosphate, monobasic, dihydrate 13472-35-0
water 7732-18-5

New York City Hazardous Substances

SODIUM PHOSPHATE DIBASIC 7558-79-4

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.

California List of Hazardous Substances

SODIUM PHOSPHATE DIBASIC 7558-79-4

Other regulations

For professional users only.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

J&J OEL/PBOEL HHC : J&J OEL/PBOEL HHC
J&J OEL/PBOEL HHC / : PBOEL-HHC
PBOEL-HHC

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals;

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OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 2024/12/03

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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