



Aranesp® Safety Data Sheet

Revision Number: 7

Date Issued 31-Mar-2026

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

1.1 Product identifier

Product Name: Aranesp®
Common Name: Darbepoetin alfa
Chemical Name: Erythropoietin [30-asparagine, 32-threonine, 87-valine, 88-asparagine, 90-threonine]
Synonyms: Darbepoetin alfa, Novel Erythropoiesis Stimulating Protein (NESP), AMG 033

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use: Pharmaceutical
Uses advised against: No information available

Manufacturer:

Amgen Australia Pty Ltd Level 11, 10
Carrington Road Sydney, NSW 2000
Tel: 1800 803 638

Emergency Telephone Number:

Chemtrec
NORTH AMERICA 1-800-424-9300,
INTERNATIONAL 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

Pharmaceutical product intended for clinical and commercial manufacturing purposes only. Product contains darbepoetin alfa, a recombinant protein. The safety and efficacy of this product have been demonstrated in studies for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis, and for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy. Avoid inhalation, ingestion, skin contact and eye contact. Does not meet GHS classification criteria and therefore is not classified.

2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable)
REGULATION (EC) No 1272/2008, WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA)

Does not meet GHS classification criteria and therefore is not classified. Not classified

2.2 Label elements

Does not meet GHS classification criteria and therefore is not classified. Not classified

2.3 Other Hazards No information available



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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Ingredients: Darbepoetin alfa is manufactured as a polysorbate formulation and is distributed in Pre Filled Syringes (PFS) and vials. The PFS doses range from 10 to 500 mcg , which are produced using product strengths between 25 to 500 mcg/mL and filled to volumes of 0.3 to 1 mL. The vial doses range from 25 to 300 mcg and are filled to volumes of 0.75 to 1 mL.

Chemical Name: Erythropoietin [30-asparagine, 32-threonine, 87-valine, 88-asparagine, 90-threonine]
CAS-No: 209810-58-2

4. FIRST AID MEASURES

4.1 Description of first-aid measures

Eye Contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

Inhalation: Move to fresh air. If symptoms persist, call a physician.

Ingestion: If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

Notes to Physician: Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Flammable Properties: Not applicable.

Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Hazardous Combustion Products: None

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.



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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Spill Procedures:

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Handling and Storage:

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limit: No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 6 µg/m³ as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Darbepoetin alfa has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 4 compound (5 µg/m³ - 20 µg/m³).

Engineering Controls: When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

8.2 Exposure controls

Personal Protective Equipment

Eye/face Protection: Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

Skin Protection: Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

Respiratory Protection: When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed. The choice of protection should be based on the job activity and the potential for exposure.

Other: Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

8.3 Environmental exposure controls

Environmental Exposure Controls Avoid release to the environment.



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9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---------------------------|
| Appearance: | Clear Colorless to yellow |
| Physical State: | Liquid |
| Molecular Weight: | ~ 37,000 daltons |
| Odor: | No information available |
| Odor Threshold: | No information available |
| pH: | 6.2 |
| Melting Point: | No information available |
| Boiling point | No information available |
| Flash Point: | No information available |
| Evaporation Rate: | No information available |
| Lower explosive limit: | No information available |
| Upper explosive limit: | No information available |
| Vapor Pressure: | No information available |
| Vapor Density (air = 1): | No information available |
| Relative density: | No information available |
| Water Solubility: | No information available |
| Partition Coefficient (log Kow): | 0.98 |
| Viscosity: | No information available |

10. STABILITY AND REACTIVITY

| | |
|--|--------------------------|
| 10.1 Reactivity | No information available |
| 10.2 Chemical stability | Stable |
| 10.3 Possibility of hazardous reactions | No information available |
| 10.4 Conditions to avoid | No Information available |
| 10.5 Incompatible materials | No information available |
| 10.6 Hazardous decomposition products | No information available |
| 10.7 Other information | None |



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11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

| | |
|---|---|
| Acute Toxicity: | No information available |
| Skin corrosion/irritation: | Does not meet GHS Classification Criteria and therefore is not classified. |
| Serious eye damage/eye irritation: | Does not meet GHS Classification Criteria and therefore is not classified. |
| Respiratory or skin sensitization: | Does not meet GHS Classification Criteria and therefore is not classified. |
| Germ cell mutagenicity: | Not genotoxic based on a battery of in vitro and in vivo studies. Based on available data, the GHS classification criteria are not met. |
| Carcinogenicity: | Does not meet GHS Classification Criteria and therefore is not classified. |
| Reproductive toxicity: | Does not meet GHS Classification Criteria and therefore is not classified. |
| STOT - single exposure: | Does not meet GHS Classification Criteria and therefore is not classified. |
| STOT - repeated exposure: | Does not meet GHS Classification Criteria and therefore is not classified. |
| Aspiration Hazard: | No information available |

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity effects: No information available

12.2 Persistence and degradability

Persistence/Degradability: No information available

12.3 Bioaccumulative potential

Bioaccumulation/ Accumulation: No information available

12.4 Mobility in soil

Mobility in Environmental Media: No information available

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: No information available

12.6 Other adverse effects

Other Adverse Effects: No information available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste Disposal Method: Dispose of waste according to prescribed federal, state, local and competent authority guidelines.



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14. TRANSPORT INFORMATION

DOT: Not regulated by U.S. DOT, IATA, ADR, or IMDG.

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

| | |
|----------------------|---|
| TSCA: | - |
| EINECS/ELINCS | - |
| DSL/NDSL | - |
| PICCS: | - |
| ENCS: | - |
| CHINA: | - |
| AICS: | - |
| KECL: | - |

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

State Regulations

California Proposition 65: This product does not contain any Proposition 65 chemicals.

15.2 Chemical safety assessment

No CSA has been conducted.



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16. OTHER INFORMATION

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The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections, which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it may be biologically active. Translation of this SDS is available upon request.

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