



**1. Identification of the substance/preparation and of the company**

**Product name** PROLEUKIN<sup>®</sup> (aldesleukin) for injection, for intravenous infusion  
**Synonyms** Recombinant Human Interleukin-2 (IL-2); Aldesleukin  
**Company name** Prometheus Laboratories Inc.  
9410 Carroll Park Drive  
San Diego, CA 92121  
Tel: 888-423-5227  
mail: customer.service@prometheuslabs.com

**Emergency phone number** 888-423-5227

**Usage** Treatment of metastatic renal cell carcinoma (kidney cancer) and metastatic melanoma (skin cancer).

**2. Hazards identification**

**FINISHED PHARMACEUTICAL PRODUCT**

**Refer to physicians' Desk Reference**

**Affects Blood-Forming Organs**

**May Cause Muscle Pain and Fatigue**

**May Cause Nausea and Vomiting,**

**May Cause Mild Eye and Skin Irritation**

**May Cause Abdominal Pain and Diarrhea**

**Effects of Overexposure:** Finished pharmaceutical product. Potential for exposure is reduced in this form

**Skin:** May mildly irritate the skin.

**Eye:** May cause mechanical irritation (i.e., foreign object)

**Inhalation:** No hazard is expected from normal clinical use.

**Ingestion:** No hazard is expected from normal clinical use.

**Therapeutic Side Effects:** May impair the cardiac, pulmonary, hepatic, renal neurologic, endocrine or gastrointestinal systems. Symptoms after injection may include fever, chills, joint pain, muscle pain, fatigue, inflammation and/or nodules at the injection site, nausea, vomiting, anorexia, diarrhea, abdominal discomfort, reduced platelet count and anemia. Most changes are reversible. High doses did produce capillary leak syndrome.

**Target Organ Effects:** Affects the hematologic system.

**Reproductive Hazards:** No evidence of developmental effects or reproductive toxicity. Embryotoxicity observed at maternally toxic doses. (See section 11)

**Carcinogenicity:** Not carcinogenic

Not Listed on: IARC, NTP, FEDERAL OSHA Z-List, CAL-OSHA

**Mutagenicity:** No tests have been performed to assess mutagenic potential

**Medical Conditions Aggravated by Exposure:** Auto-immune disorders.



**3. Composition / information on ingredients**

<u>Chemical Name</u>	<u>CAS#</u>	<u>Concentration (% By Wt.)</u>
Mannitol	69-65-8	5.0
Recombinant Human Interleukin-2	Not available	0.11
Sodium Dodecyl Sulphate	151-21-3	0.018
Sodium Phosphate, Dibasic	7558-79-4	0.089
Sodium Phosphate, Monobasic Monohydrate	10049-21-5	0.017
Purified water	7732-18-5	Balance

**4. First aid measures**

<b>Skin Contact</b>	Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical attention if adverse effects develop.
<b>Eye Contact</b>	Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Seek Medical attention if adverse effects develop.
<b>Inhalation</b>	Remove victim to fresh air. Seek immediate medical attention and show the label where possible.
<b>Ingestion</b>	If swallowed, seek medical attention immediately and show the label where possible

**5. Fire fighting measures**

<b>Suitable Extinguishing Media</b>	Water spray or fog, foam, dry chemical powder, CO2, dry sand
<b>Unsuitable Extinguishing Media</b>	No restrictions
<b>Protective equipment for firefighters</b>	Wear self-contained breathing apparatus and fire protective suit.

**6. Accidental release measures**

<b>Personal precautions</b>	Avoid contact with skin, eyes and clothing.
<b>Environmental precautions</b>	Must not be released into sewers, drains or wells.
<b>Methods for cleaning</b>	Using appropriate protective equipment transfer large quantities into a container. All contaminated areas should be thoroughly cleaned with detergent solution and rinsed with clean water. Avoid contamination of sewers and water ways.

**7. Handling and storage**

<b>Storage Temperature (min./Max.):</b>	2-8°C(36-46°F)
<b>Shelf Life:</b>	Refer to Package Insert
<b>Special Sensitivity:</b>	Protect from light
<b>Handling and Storage Precautions:</b>	Store product away from strong oxidizers



**8. Exposure controls / Personal protection**

**Eye Protection:** Safety glasses with side-shields or chemical splash goggles should be worn in the event airborne dust is generated prior to product reconstitution

**Skin Protection:** Disposable nitrile or neoprene gloves are recommended. Use double gloves for spill response. Use glove type appropriate to the solvent in use with the product.

**Respiratory Protection:** Generally not required under normal conditions of therapeutic administration and use.

**Ventilation Requirements:** Use adequate ventilation. Follow standard medical handling procedures. If the generation of airborne dust is anticipated during product manipulation prior to reconstitution, the use of a drug safety cabinet or powder weighing hood is recommended.

**Additional Measures:** The use of a disposable protective gown or lab coat is recommended to prevent exposure of this product to personal clothing

**Exposure Limits**

<u>Component</u>	<u>PEL* mg/m3</u>	<u>STEL* mg/m3</u>
Mannitol	NE	NE
Recombinant Human Interleukin-2	NE	NE
Sodium Dodecyl Sulphate	NE	NE
Sodium Phosphate, Dibasic	NE	NE
Sodium Phosphate, Monobasic Monohydrate	NE	NE

\*PEL: Permissible Exposure Limit      STEL: Short Term Exposure Limit

**9. Physical and chemical properties**

<b>Appearance:</b>	lyophilized cake	<b>Odor Threshold:</b>	odorless
<b>Color:</b>	white to off-white	<b>Vapor Pressure (mm Hg):</b>	not established
<b>pH:</b>	7.2-7.8 (reconstituted)	<b>Vapor Density:</b>	not established
<b>Boiling Point:</b>	not applicable	<b>Specific Gravity:</b>	not established
<b>Melting Point/Range:</b>	not established	<b>%volatile by Wt:</b>	not established
<b>Freezing Point:</b>	not established	<b>Viscosity:</b>	not applicable
<b>Soluble in:</b>	water		

**10. Stability and reactivity**

**Stable (yes/no):** yes

**Hazardous Polymerization:** Will not occur

**Conditions and Materials to Avoid:** Protect from light and incompatible chemicals

**Incompatibility:** Strong oxidizers

**Hazardous Decomposition products:** Sodium and carbon oxides

**11. Toxicological information**

Acute Toxicity      no data available

Skin corrosion/Irritation      no data available

Serious eye damage/irritation      no data available

Respiratory or skin sensitization      no data available

Germ cell mutagenicity      unknown no studies have been performed

Carcinogenicity      Not suspected of having carcinogenic potential



## SAFETY DATA SHEET

Reproductive toxicity	No evidence of teratogenicity was observed at any dose level in studies in rats. In embryo-fetal toxicity studies, maternal toxicity, including death, was observed in pregnant rats administered 0.5 to 4.0 mg/kg of IL-2 by intravenous injection. Reduced implantations and increased early resorptions were seen at 3.0 and 4.0 mg/kg, resulting in reduced live litter sizes. These effects were attributed to the observed maternal toxicity. No changes in the number of implantations or resorptions were observed at $\leq 1$ mg/kg in rats.
STOT-single exposure	no data available
STOT-repeated exposure	no data available
Aspiration hazard	no data available
SubChronic	Mutidose studies were performed in mice, rats, rabbits, and cynomolgus monkeys with the majority conducted via the intravenous or subcutaneous route. Findings in these studies included lymphocytosis, eosinophilia, slight anemia, extramedullary hematopoiesis, hepato-splenomegaly, and lymphoid hyperplasia as well as infiltrative and proliferative changes in many organs (including liver, lung lymph nodes, kidney, spleen, and bone marrow). A slight reversible elevation in heart rate and body temperature was also noted in telemetered primates. In all species studied, toxicity was partially or fully reversible following a treatment-free recovery phase.
<b>12. Ecological information</b>	
The components of this product are relatively stable in the environment. The ecotoxicological properties have not been fully investigated	
<b>13. Disposal considerations</b>	
<b>Disposal Requirements</b>	Incineration in an approved controlled furnace with combustion gas scrubbing and emission gas control. All wastes must be disposed of in accordance with local, state and federal laws and regulations. Avoid disposal in sewers and waterways.
<b>Container Disposal</b>	For disposal local regulation is binding.
<b>EPA Hazardous Waste Number</b>	None
<b>14. Transport information</b>	
<b>Ground Regulations:</b>	
Proper Shipping Description: Drugs, N.O.I., NMFC Item 60000	
Other Requirements: Not Applicable	
<b>Air Regulations:</b>	
Proper Shipping Description: Drugs, N.O.I., NMFC Item 60000	
Other Requirements: Not Applicable	



**15. Regulatory information**

**OSHA (Occupational Safety & Health Administration):** This Safety Data Sheet contains the information required by the Federal OSHA Hazard Communications Standard (29CFR 1910.1200).

**OSHA PSM (Process Safety Management):** Not listed (29CFR 1910.119, Appendix A)

**NJ TCPA (Toxic Catastrophe Prevention Act):** This product contains NONE of the substances subject to the reporting requirements of Section .J.A.C. 7:31 of this Act.

**TSCA (Toxic Substance Control Act):** Exempt from the requirements of TSCA.

**CERCLA (Comprehensive Response Compensation & Liability Act):** Not applicable

**SARA Title III (Superfund Amendments & Reauthorization Act):**

Section 3.2 Extremely Hazardous Substances:	Not listed
Section 311/312 Hazard Categories:	Acute health effects, chronic health effects
Section 313 Reportable Ingredients:	Not listed

**RCRA (Resource Conservation & Recovery Act):**

Not listed

**Other State Regulatory Information:**

New Jersey: NJ RTK Threshold Planning Quantity = 10,000 lbs.

**Other USA Regulations:** None

**California Proposition 65:** The following statement is made in order to comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986. This product contains no chemicals known to the State of California to cause cancer or reproductive toxicity.

**Canada:** WHMIS Ingredient Disclosure List

Not listed

**EU Classification:** Hazard Symbol:

Not available

Risk Phrases:

No applicable

Safety Phrases:

Not applicable

**16. Other information**

**Revision Date:** March 2015

To the best of our knowledge, the information contained herein is accurate. However Prometheus Laboratories Inc. does not assume any liability whatsoever for the accuracy or completeness of the information contained herein except for the product's administration/use as intended. Final determination of the suitability of any materials the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards which exist.