

Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • Iprivask® (desirudin for injection)

Product Code • NDC 0187-0011-10; NDC 0187-0012-01

Product Description • Prescription pharmaceutical product.

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

Recommended use • Iprivask is indicated for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals North America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Reproductive Toxicity 2

Label elements

UN GHS

WARNING



Hazard statements • Suspected of damaging fertility or the unborn child.

Precautionary statements

Prevention • Wash thoroughly after handling.

Do not handle until all safety precautions have been read and understood.
 Avoid breathing dust, fume, gas, mist, vapours and/or spray.
 Use personal protective equipment as required.

- Response** • IF exposed: Call POISON CENTER or doctor/physician.
- Storage/Disposal** • Store in a well-ventilated place. Keep container tightly closed.
 Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

- UN GHS** • No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Iprivask- Desirudin, lyophilized		> 50%	UN GHS: NDA
Desirudin	CAS:120993-53-5	N/A	UN GHS: NDA
Magnesium chloride	CAS:7786-30-3 EINECS:232-094-6	N/A	UN GHS: Eye Irrit. 2B; Acute Tox. Oral 5
Sodium hydroxide	CAS:1310-73-2 EINECS:215-185-5	N/A	UN GHS: Skin Corr. 1A
Iprivask solvent ampoule		< 50%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	N/A	UN GHS: NDA
Mannitol, D-	CAS:69-65-8 EINECS:200-711-8	N/A	UN GHS: NDA

Iprivask (desirudin for injection) is supplied as a single dose (15.75 mg) lyophilized powder with an accompanying sterile, non-pyrogenic diluent [0.6 mL of Mannitol USP (3%) in Water for Injection].

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

Skin

- Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately before reuse.

Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion

- If swallowed, wash out mouth with water provided person is conscious. Seek medical attention.

Most important symptoms and effects, both acute and delayed

- Emergency procedures should be instituted as appropriate (for example, determination of aPTT and other coagulation levels, hemoglobin, the use of blood transfusion or plasma expanders).

Indication of any immediate medical attention and special treatment needed

Notes to Physician

- Hemorrhage: Bleeding can occur at any site with exposure to Iprivask. An unexplained fall in hematocrit or blood pressure should lead to a search for a bleeding site. Avoid intramuscular injection as local bleeding and hematoma formation may result.

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Additional details are available on the product package insert or the Physicians Desk Reference.

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media**
- SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
 - LARGE FIRE: Water spray, fog or regular foam.

- Unsuitable Extinguishing Media**
- No data available

- Firefighting Procedures**
- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- None known - product is not flammable or combustible.

- Hazardous Combustion Products**
- No data available

Advice for firefighters

- Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Evacuate immediate area. Ventilate enclosed areas.

- Emergency Procedures**
- Keep unauthorized personnel away. For bulk material spills: Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Ventilate closed spaces before entering.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

- Containment/Clean-up Measures**
- Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete. Refer to Section 13 for appropriate disposal procedures.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- Use only in well ventilated areas (preferably in a chemical fume hood). Do not breathe dusts, vapors or mists. Do not get in eyes, on skin, or on clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at controlled room temperature 25°C/77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Sodium hydroxide (1310-73-2)	Ceilings	2 mg/m ³ Ceiling	2 mg/m ³ Ceiling	2 mg/m ³ Ceiling	Not established
	TWAs	Not established	Not established	Not established	2 mg/m ³ TWA

Exposure controls

Engineering Measures/Controls

- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Pictograms



Respiratory

- Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. Not required during normal clinical use.

Hands

- Wear protective gloves .

Skin/Body

- Wear protective gloves/protective clothing/eye protection/face protection. Not required during normal clinical use.

General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke during work. Avoid contact with skin, eyes or clothing. Wash thoroughly after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid and Solid	Appearance/Description	Two vials - one containing white to off-white lyophilized powder and one containing a clear liquid.
Color	White	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	6.5 to 7.5
Specific Gravity/Relative Density	No data available	Water Solubility	Soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and humidities.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- This product is generally compatible with other common materials in a medical facility.

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met

Skin corrosion/Irritation	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 2
STOT-SE	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met

Target Organs

- Blood

Potential Health Effects**Inhalation****Acute (Immediate)**

- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

- No data available

Skin**Acute (Immediate)**

- Non-irritating to skin or mucous membranes when used as directed.

Chronic (Delayed)

- No data available

Eye**Acute (Immediate)**

- May cause mild eye irritation with direct contact to eye.

Chronic (Delayed)

- No data available

Ingestion**Acute (Immediate)**

- Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.

Chronic (Delayed)

- No data available

Other**Acute (Immediate)**

- Avoid intramuscular injection of Iprivask as bleeding and local hematoma formation can occur. Iprivask increases the risks of hemorrhage in patients with recent major surgery, organ biopsy or puncture of a non-compressible vessel within the last month; a history of hemorrhagic stroke, intracranial or intraocular bleeding including diabetic (hemorrhagic) retinopathy; recent ischemic stroke, severe uncontrolled hypertension, bacterial endocarditis, a known hemostatic disorder (congenital or acquired, e.g. hemophilia, liver disease) or a history of gastrointestinal or pulmonary bleeding within the past 3 months.

Carcinogenic Effects		
	CAS	NTP
Mannitol, D-	69-65-8	Evidence of Carcinogenicity

Section 12 - Ecological Information**Toxicity**

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects**Section 13 - Disposal Considerations****Waste treatment methods****Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture**

SARA Hazard Classifications • Acute

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Desirudin	120993-53-5	No	No	No
Magnesium chloride	7786-30-3	Yes	Yes	Yes
Mannitol, D-	69-65-8	Yes	Yes	Yes
Sodium hydroxide	1310-73-2	Yes	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

- Magnesium chloride

7786-30-3

Uncontrolled product according to WHMIS classification criteria E (including 0.04% in aqueous

• Sodium hydroxide	1310-73-2	solution, 0.04N, 0.08%, 0.4% in aqueous solution, 2%, 2.5%, 4% in aqueous solution, 5%, 10%, 16%, 20%, 40%, 50% in aqueous solution, 8.7N)
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	1 %
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

Europe**Other****EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification**

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	C; R35
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Concentration Limits

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	5%≤C: C; R:35 2%≤C<5%: C; R:34 0.5%≤C<2%: Xi; R:36/38
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	C R:35 S:(1/2)-26-37/39-45
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	S:(1/2)-26-37/39-45
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	1000 lb final RQ; 454 kg final RQ
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

United States - California

Environment**U.S. - California - Proposition 65 - Carcinogens List**

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Magnesium chloride	7786-30-3	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Desirudin	120993-53-5	Not Listed
• Mannitol, D-	69-65-8	Not Listed

Section 16 - Other Information**Revision Date**

- 28/January/2016

Last Revision Date

- 28/January/2016

Preparation Date

- 28/January/2016

Disclaimer/Statement of Liability

- To the best of our knowledge, the information contained herein is accurate. However, neither Valeant Pharmaceuticals International, Inc. nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is 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 that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Valeant Pharmaceuticals International, Inc. or any of its subsidiaries be liable for any special, incidental or consequential damages.