

PROSTASCINT SAFETY DATA SHEET

Section 1 – Identification of the Substance/Preparation and the Company/Undertaking

1.1 Product Identifier

Trade Name (As Labeled): ProstaScint
Synonym(s): Capromab Pendetide, CYT-356
Chemical Name/Class: Mixture
U.N. Number: Not Applicable
U.N. Dangerous Goods Class/Subsidiary Risk: Not Applicable
How Supplied: 2 vials to produce single IV dose
Date of Preparation: March 9, 2016

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Product Use: Detection of Prostate Cancer
Uses Advised Against: All other uses

1.3 Details of the Supplier of the Substance or Mixture

Supplier/Manufacturer's Name: Aytu BioScience, Inc.
Address: 373 Inverness Parkway, Suite 206
Englewood, Colorado 80112 USA
Phone: +1-720-437-6580
Email address: info@aytubio.com

1.4 Emergency Telephone Number

+1-855-298-8246 (in US)
+1-855-298-8246 (from outside US)

Section 2 - Hazards Identification

2.1 Classification of the Substance or Mixture

CLP/GHS Classification (1272/2008): Not Hazardous

Note: Medicinal products as defined in Directive 2001/83/EC in their finished state, intended for the final user are not subject to the EU Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (Reg. No 1272/2008) or the requirement in REACH for a safety data sheet.

2.2 Label Elements

No GHS/CLP Labelling Required

2.3 Other Hazards: None

Section 3 - Composition Information on Ingredients

3.2 Mixture

Chemical Name	CAS Number / EINECS Number / REACH Reg. Number	% (w/w)	CLP/GHS Classification (1272/2008)
ProstaScint Vial			
Capromab pendetide	Not Assigned	0.5 mg/vial	Not Hazardous

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Sodium phosphate buffered saline	Mixture	1 mL/vial	Not Hazardous
Sodium Acetate Buffer Vial			
Sodium Acetate	6131-90-4 / 204-823-8	82 mg/vial 3.9%	Not Hazardous
Water for injection	7732-18-5/231-791-2	2 ml/vial	Not Hazardous

Section 4 - First Aid Measures

4.1 Description of First Aid Measures

Skin Exposure: Remove contaminated clothing. Wash contact area thoroughly with soap and water. If irritation persists or other symptoms develop, get medical attention.

Eye Exposure: If this material contaminates the eyes, flush eyes with gently running water for several minutes. If irritation persists or other symptoms develop, get medical attention.

Inhalation: Inhalation is an unlikely route of exposure for this material. If aerosols or mists of this material are inhaled, remove victim to fresh air. If irritation persists or other symptoms develop, get medical attention.

Ingestion: Ingestion is not anticipated to be a significant route of overexposure. If this material is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, DO NOT induce vomiting: Have the victim rinse their mouth and drink 2 glasses of water. Never induce vomiting or give diluents (water) to someone who is unconscious, having convulsions, or unable to swallow.

4.2 Most Important symptoms and effects, both acute and delayed: May cause mild eye and skin irritation. Inhalation of mists may cause an allergic reaction in some individuals.

4.3 Indication of Immediate Medical Attention and Special Treatment, If Needed: Seek medical attention if any adverse effects occur.

Section 5 - Fire-Fighting Measures

5.1 Suitable Extinguishing Media: Use any media that is suitable for the surrounding fire.

5.2 Specific Hazards Arising from the Chemical: This product is not flammable or combustible. When involved in a fire, products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides).

5.3 Special Protective Equipment and Precautions for Fire Fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for fires in areas where chemicals are used or stored.

Section 6 - Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures: Clear spill area of unprotected people. Responders should wear appropriate protective clothing to avoid contact with material (see section 8).

6.2 Environmental Precautions: Avoid release to the environment. Report spills are required by local and national authorities.

6.3 Methods And Materials For Containment/Cleanup: Absorb small spills with paper towels or damp sponge. Rinse area with soap and water solution and follow with a water rinse. Decontaminate the area thoroughly. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable U.S. Federal, State, or local procedures or appropriate standards Canada or EU Member States (see Section 13, Disposal Considerations).

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Section 7 - Handling and Storage

- 7.1 Precautions for Safe Handling:** Avoid contact with eyes, skin and clothing. Avoid creating and breathing aerosols or mists. Wash thoroughly after handling this material or equipment and containers that have been in contact with this material. Do not eat, smoke or drink while handling this product. Remove contaminated clothing immediately. Follow SPECIFIC USE INSTRUCTIONS supplied with this material. Radiopharmaceuticals should be used only by physicians and other professionals who are qualified by training and experience in the safe use and handling of radionuclides. The contents of the kit are not radioactive. However, after the Indium In 111 chloride is added, appropriate shielding of Indium In 111 ProstaScint® (capromab pendetide) must be maintained. Care should be taken to minimize radiation exposure to patients and medical personnel, consistent with proper hospital and patient management procedures.
- 7.2 Conditions for Safe Storage, Including Any Incompatibilities:** Store as directed on the package insert.
- 7.3 Specific end use(s):**
Industrial uses: None identified
Professional uses: Pharmaceutical use only

Section 8 - Exposure Controls / Personal Protection

8.1 Control Parameters

CHEMICAL	EXPOSURE LIMIT
Capromab pendetide	None Established
Sodium phosphate buffered saline	None Established
Sodium Acetate	None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: No special ventilation is required for normal use. Use with adequate ventilation to minimize exposure. Follow standard medical material handling procedures.

Personal Protective Equipment

Respiratory Protection: Respiratory protection is not generally needed during routine use of this material. If mists or aerosols are generated, appropriate respiratory protection should be worn. Equipment selection depends on contaminant type and concentration. Select and use in accordance with 29 CFR 1910.134 or other applicable regulations and good industrial hygiene practice. For firefighting, use self-contained breathing apparatus.

Eye Protection: Splash goggles or safety glasses if needed to avoid eye contact. If necessary, refer to U.S. OSHA 29 CFR 1910.133, appropriate Canadian Standards, or the European Standard EN166 for further information.

Hand Protection: Wear latex, rubber or nitrile gloves for routine use. If necessary, refer to U.S. OSHA 29 CFR 1910.138, EN Standards or appropriate Standards of Canada.

Other Protective Equipment/Clothing: Appropriate protective clothing as needed to minimize skin contact. Suitable washing and eye flushing facilities should be available in the work area. Contaminated clothing should be removed and laundered before re-use.

Section 9 - Physical and Chemical Properties

9.1 Information on basic Physical and Chemical Properties

Appearance:	Clear, colorless liquid in glass vials	Odor:	Odorless
Odor Threshold:	Not applicable	pH:	5-7
Melting/Freezing Point:	Not established	Boiling Point/Range:	Not established
Flash Point:	None	Evaporation Rate:	Not established
Flammability (Solid,	Not Applicable	Flammability Limits:	None

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Gas)			
Vapor Pressure:	Same as water	Vapor Density:	Same as water
Relative Density:	Not established	Solubilities	Water: 100%
Partition Coefficient (n-Octanol/Water)	Not established	Autoignition Temperature:	None
Decomposition Temperature:	Not established	Viscosity:	Not established
Explosive Properties:	None	Oxidizing Properties:	None

9.2 Other Information: None available

Section 10 - Stability and Reactivity

10.1 Reactivity: Normally unreactive

10.2 Chemical Stability: Stable

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Exposure to or contact with extreme temperatures.

10.5 Incompatible Materials: This material is generally compatible with other common materials in a medical facility. Acids, caustics, strong oxidizers, and other chemicals that could affect its performance should be avoided.

10.6 Hazardous Decomposition Products: If exposed to extremely high temperatures, the materials of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides).

Section 11 - Toxicological Information

11.1 Information on Toxicological Effects:

POTENTIAL HEALTH EFFECTS:

Symptoms of Overexposure by Route of Exposure: The extent of entry into the body by most routes has not been fully investigated.

Inhalation: Inhalation of mists or sprays of this product may slightly irritate the nose, throat, and lungs. Capromab pendetide is a monoclonal antibody which may cause an allergic reaction if inhaled.

Skin: Skin contact with this material may be mildly irritating. Symptoms of skin contact may include redness and itching.

Eyes: Eye contact with this material may be mildly irritating. Symptoms of eye contact may include redness and tearing.

Skin Absorption: This material is not known to be absorbed through the skin.

Ingestion: Ingestion is not anticipated to be a significant route of occupational overexposure for this material. If this material is swallowed (i.e., through poor hygiene practices), it may slightly irritate the mouth and throat.

Injection: Though not anticipated to be a significant route of overexposure for this material, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection and an allergic reaction.

Toxicity Data: This product has been found to be non-toxic via IV administration.

Carcinogenicity: The components of this product are not classified as carcinogens or suspected carcinogens by OSHA, NTP, ACGIH, IARC or the EU CLP.

Irritancy of Material: This material may be mildly irritating to the eyes and slightly irritating to the skin.

Sensitization to The Material: Monoclonal antibodies may cause allergic reactions when inhaled or injected.

Reproductive Toxicity Information: This product is not intended for use in women.

Biological Exposure Indices: Currently, there are no Biological Exposure Indices (BEIs) determined for the components of this material.

Section 12 - Ecological Information

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12.1 Ecotoxicity: No data available.

12.2 Persistence And Degradability: No data available.

12.3 Bioaccumulative Potential: No data available.

12.4 Mobility In Soil: This material would be expected to be mobile in soil.

12.5 Results of PVT and vPvB assessment: Not required.

12.5 Other Adverse Effects: No data available.

Section 13 - Disposal Considerations

13.1 Preparing Wastes For Disposal: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada or EU Member States.

U.S. EPA Waste Number: Not applicable to wastes consisting only of this material.

Section 14 - Transport Information

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
US DOT	None	Not Regulated	None	None	No
Canadian TDG	None	Not Regulated	None	None	No
EU ADR/RID	None	Not Regulated	None	None	No
IMDG	None	Not Regulated	None	None	No
IATA/ICAO	None	Not Regulated	None	None	No

14.6 Special Precautions for User: None

14.7 Transport in Bulk According to Annex III MARPOL 73/78 and the IBC Code: Not applicable, transported only in packaged form

Section - 15 Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: This material is not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: There are no specific Threshold Planning Quantities for this material. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantity (RQ): Not applicable.

U.S. TSCA Inventory Status: This material is regulated by the Food and Drug Administration; it is exempt from the requirements of TSCA.

California Safe Drinking Water and Toxic Enforcement Act {PROPOSITION 65}: This material is not on the California Proposition 65 list.

CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: This material is regulated by the Therapeutic Materials Programme (TPP) of Health Canada; it is exempt from the requirements of CEPA.

Canadian WHMIS IDL Disclosure Status: Not applicable.

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Canadian Environmental Protection Agency (CEPA) Priority Substances Lists: This material is not on the Priority Substances Lists.

EUROPEAN UNION INFORMATION FOR MATERIAL:

EU Labeling and Classification: European UNION Reg. No 1272/2008 is not applicable to medicinal product.

GERMAN INFORMATION FOR THE MATERIAL:

Aquatic Hazard Class (WGK): This material does not have a specific WGK classification assigned. As such, the classification for this product, per the VwVS regulations is WGK 1.

Technical Instruction on Air Quality Control (TALuft): This material does not have a specific TALuft Classification.

NORWEGIAN INFORMATION FOR MATERIAL:

Environmental Pollutants: This material is not listed as Environmental Pollutants by the State Pollution Control Authority in Norway.

SWEDISH INFORMATION FOR THE MATERIAL:

Swedish National Chemicals Inspectorate's List Of Carcinogenic Substances: This material is not on the National Chemicals Inspectorate's list of Carcinogenic Substances.

Swedish National Chemicals Inspectorate's Esther Manual: This material is not an ESTHER Substance.

Swedish High Volume Chemicals: This material is not on the list of Swedish High Volume Chemicals. This is the list of 1 000 compounds that are of the highest volume produced or imported into Sweden.

Other Swedish Regulations: This material is not on the Swedish list of Environmentally Hazardous Chemicals.

Section 16 - Other Information

CLP/GHS Classification and H Phrases for Reference (See Section 3)

None

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Disclaimer: The above mentioned information is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. The information in this document is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. It does not represent any guarantee of the properties of the product. Aytu BioScience shall not be held liable for any damage resulting from handling or use of this product.