

# Kit SDS Cover Sheet

Doc. ID: A16972-75: Rev. AD  
Revised (year/month/day) 2010/11/25

## Product Information

<b>Product Name</b>	PTH
<b>Part Number</b>	A16972
<b>Series Name</b>	ACCESS®
<b>Additional Product Information</b>	For In Vitro Diagnostic Use. See product literature for details.

## Components

### Description

Paramagnetic Particles (Compartment R1a)  
Reagent (Compartment R1b)  
Conjugate (Compartment R1c)


## Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

**SAFETY DATA SHEET**

PTH  
 Doc. ID: A16972-75 AD  
 Revised (year/month/day) 2010/11/25

**Section 1 Company and Product Identification**

<b>Product Name</b>	Paramagnetic Particles (Compartment R1a)
<b>Part Number</b>	Component of P/N A16972
<b>Product Use</b>	For In Vitro Diagnostic Use. See product literature for details.
<b>Series Name</b>	ACCESS®
<b>Manufacturer</b>	Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633 <b>E-mail:</b> SDSNT@beckman.com
<b>EC REP Address</b>	Beckman Coulter Ireland Inc. Mervue Business Park Mervue, Galway, Ireland Tel: 353 91 774068
<b>Distributor and Emergency Phone No.</b>	 Refer to attached list, Document ID: <a href="#">472050</a> , for local distributor and emergency phone numbers.

**Section 2 Hazards Identification**

<b>Emergency Overview</b>	<p><b>Orange; Opaque; Liquid - Suspension; Odorless</b>  <b>Nonflammable aqueous solution.</b>  <b>May cause sensitization by skin contact.</b>  <b>Skin, eye and respiratory tract irritant.</b>  <b>Contains material of animal origin.</b></p>
<b>Physical Hazards</b>	Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
<b>Potential Health Effects Summary</b>	May cause sensitization by skin contact. Exposure may result in irritation of skin, eyes, and mucous membranes. This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases. See Section 11 Toxicological Information for more detailed health information.
<b>Potential Environmental Effects</b>	Not available

## Section 2 Hazards Identification (Continued)

Product Hazard Classifications	Meets Hazardous Criteria for Preparation/Mixture		
	EU: Xi;R43	WHMIS: Exempt	US OSHA: Hazardous

## Section 3 Composition and Information on Ingredients

Hazardous Ingredients:				Hazard Classification of Pure Ingredients		
Chemical Name	CAS #	EINECS #	% by wt.	EU	WHMIS	US OSHA
Tris(hydroxymethyl)-aminomethane	77-86-1	2010644	< 2	Xi;R36/37/38	D2B	Irritant
ProClin* 300	Not available	Not available	< 0.6	C;R34-43-20/21/22 N;R51/53	D2B	Corrosive Sensitizer

See Section 15 Regulatory Information for additional information on hazard classifications.

See Section 16 for Risk Phrases and WHMIS Classification Description.

## Section 4 First Aid Measures

<b>Inhalation</b>	If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.
<b>Eye Contact</b>	If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.
<b>Skin Contact</b>	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.
<b>Ingestion</b>	If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

## Section 5 Fire Fighting Measures

<b>Flammable Properties</b>	Nonflammable aqueous solution.
<b>Extinguishing Media</b>	Use extinguishing media suitable for surrounding fire.
<b>Special Fire and Explosion Hazards</b>	No special hazards determined.
<b>Hazardous Combustion Products</b>	No combustion products posing significant hazards are expected from this product (an aqueous solution).
<b>Protective Equipment for Firefighters</b>	Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

## Section 6 Accidental Release Measures

<b>Personal Precautions</b>	This product contains material of animal origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed during clean up procedures.
<b>Spill and Leak Procedures</b>	As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
<b>Environmental Precautions</b>	Contain spill to prevent migration.

## Section 7 Handling and Storage

<b>Handling Precautions</b>	This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.
<b>Recommended Storage Conditions</b>	Keep away from incompatible material (see Section 10). To maintain efficacy, store according to the instructions in the product labeling.

## Section 8 Exposure Controls and Personal Protection

<b>Exposure Limits</b>	
<b>US OSHA:</b>	None established
<b>ACGIH:</b>	None established
<b>DFG MAK:</b>	None established
<b>NIOSH</b>	None established
<b>Japan</b>	None established
<b>Engineering Controls</b>	No special engineering controls are required. Use with good general ventilation.
<b>Respiratory Protection</b>	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.
<b>Eye Protection</b>	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
<b>Skin Protection</b>	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

## Section 9 Physical and Chemical Properties

<b>Physical State</b>	Liquid - Suspension
<b>Color</b>	Orange

## Section 9 Physical and Chemical Properties (Continued)

<b>Transparency</b>	Opaque
<b>Odor</b>	Odorless
<b>Odor Threshold</b>	Not applicable
<b>pH</b>	8
<b>Freezing Point</b>	Not available
<b>Boiling Point</b>	Not available
<b>Flash Point</b>	Not applicable
<b>Evaporation Rate</b>	Not available
<b>Flammability (Solid, Gas)</b>	Not applicable
<b>Flammable Limits</b>	Not available
<b>Vapor Pressure</b>	Not available
<b>Vapor Density</b>	Not available
<b>Specific Gravity</b>	≈ 1 @20°C
<b>Solubility</b>	
<b>Water</b>	Miscible
<b>Organic</b>	Not available
<b>Coefficient of Water/Oil Distribution</b>	Not available
<b>Autoignition Temp.</b>	Not applicable
<b>Decomposition Temperature</b>	Not available
<b>Percent Volatiles</b>	Not available

## Section 10 Stability and Reactivity

<b>Stability</b>	Stable under normal temperatures and pressures.
<b>Hazardous Incompatibilities</b>	<p>Strong acids            Strong bases            Strong oxidizers            Metals and metallic compounds</p> <p>Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide &lt;0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.</p>

## Section 10 Stability and Reactivity (Continued)

<b>Hazardous Decomposition Products</b>	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).
<b>Conditions to Avoid</b>	Avoid contact with incompatible materials.

## Section 11 Toxicological Information

### Toxicity Data for Hazardous Ingredients

Tris(hydroxymethyl)-aminomethane	Oral LD50 Rat 5900 mg/kg
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### Primary Routes of Exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

### Potential Effects of Acute Exposure

Exposure to ProClin 300 may result in irritation of skin, eyes and mucous membranes. Skin contact may result in possible sensitization. Eye contact may cause clouding of the cornea. Ingestion may cause gastrointestinal irritation; large doses given to animals resulted in collapse and coma.

Exposure to TRIS may result in irritation of skin, eyes and mucous membrane. Eye contact may result in redness, pain and corneal injury. Inhalation may result in chest pain and tightness, coughing, and difficult breathing. Ingestion may cause gastrointestinal irritation with burns to mouth and stomach, and large doses may cause weakness, collapse and death in laboratory animals.

This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

### Potential Effects of Chronic Exposure

Frequent or long-term exposure may result in conjunctivitis and dermatitis.

### Symptoms of Overexposure

Symptoms of overexposure may include: throat irritation and coughing; dry, red, cracked skin; red irritated eyes; headache, drowsiness, dizziness, stupor; convulsions and coma.

### Carcinogenicity

This product does not contain a reportable concentration ( $\geq 0.1\%$ ) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.

### Other Effects

None identified.

### Conditions Aggravated by Exposure

None identified.

## Section 12 Ecological Information

<b>Ecotoxicity</b>	No information available.
<b>Biodegradability</b>	No information available.
<b>Bioaccumulation</b>	No information available.
<b>Mobility</b>	No information available.
<b>Other Adverse Effects</b>	No information available.

### Section 13 Disposal Considerations

**Waste Disposal**

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).  
 Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

### Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

### Section 15 Regulatory Information

**US Federal and State Regulations**

**SARA 313**

Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA.  
 Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA.  
 1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA.  
 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA.  
 Zinc Chloride is subject to reporting requirements of Section 313, Title III of SARA.

**CERCLA RG's,  
 40 CFR 302.4**

Acetaldehyde is listed.  
 Ethylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.

**California Proposition 65**

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:  
**WARNING:** This product contains a chemical known to the State of California to cause cancer.  
 Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:  
**WARNING:** This product contains a chemical known to the State of California to cause cancer and reproductive harm.  
 1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:  
**WARNING:** This product contains a chemical known to the State of California to cause cancer.

**Massachusetts MSL**

Acetaldehyde is listed.  
 Ethylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.

**Section 15 Regulatory Information (Continued)**

**New Jersey Dept. of Health RTK List**

Acetaldehyde is listed.  
 Ethylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.

**Pennsylvania RTK**

Acetaldehyde is listed.  
 Ethylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.  
 Dipropylene Glycol is listed.

**EU Labeling Classification**

Classification	Risk and Safety Phrases
Irritant	R43 May cause sensitization by skin contact. S37 Wear suitable gloves. S28 After contact with skin, wash immediately with plenty of soap and water.

**Canada**

This product is exempt from WHMIS label and SDS requirements.

**PIN:** Not applicable

**Ingredients on Ingredient Disclosure List:**

Acetaldehyde  
 Ethylene Oxide  
 1,4-Dioxane  
 Zinc Chloride  
 Sodium Azide

**Ingredients with unknown toxicological properties:** Product is exempt

Some hazardous ingredients listed in Section 15 are below OSHA's and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.



## Section 16 Other Information

<b>Beckman Coulter Safety Rating</b>	<b>Flammability (Section V): 0</b> <b>Health (Section XI): 2</b> <b>Reactivity with Water (Section X): 0</b> <b>Contact (Section VIII): 2</b>	<b>Code</b> 0=none 1=slight 2=caution 3=severe
<b>Risk Phrases and WHMIS Classification Description From Section 3</b>	R20/21/22 Harmful by inhalation, in contact with skin and if swallowed. R34 Causes burns. R36/37/38 Irritating to eyes, respiratory system and skin. R43 May cause sensitization by skin contact. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in aquatic environment. D2B - Poisonous and Infectious Material: Division 2 - Other Toxic Effects: Toxic (Skin sensitization) D2B - Poisonous and Infectious Material: Division 2 - Other Toxic Effects: Toxic (Skin or Eye Irritation)	
* ProClin is a trademark of the Rohm and Haas Company.		
This SDS complies with EC Regulation 1907/2006 (REACH)		
For further information, please contact your local Beckman Coulter representative.		

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Printed in U.S.A.


**SAFETY DATA SHEET**

PTH

Doc. ID: A16972-75 AD

Revised (year/month/day) 2010/11/25

**Section 1 Company and Product Identification**

<b>Product Name</b>	Reagent (Compartment R1b)
<b>Part Number</b>	Component of P/N A16972
<b>Product Use</b>	For In Vitro Diagnostic Use. See product literature for details.
<b>Series Name</b>	ACCESS®
<b>Manufacturer</b>	Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633 <b>E-mail:</b> SDSNT@beckman.com
<b>EC REP Address</b>	Beckman Coulter Ireland Inc. Mervue Business Park Mervue, Galway, Ireland Tel: 353 91 774068
<b>Distributor and Emergency Phone No.</b>	 Refer to attached list, Document ID: <a href="#">472050</a> , for local distributor and emergency phone numbers.

**Section 2 Hazards Identification**

<b>Emergency Overview</b>	<p><b>Colorless; Clear; Liquid; Odorless</b></p> <p><b>Nonflammable aqueous solution.</b></p> <p><b>May cause sensitization by skin contact.</b></p> <p><b>Skin, eye and respiratory tract irritant.</b></p> <p><b>Contains material of animal origin.</b></p>
<b>Physical Hazards</b>	Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
<b>Potential Health Effects Summary</b>	May cause sensitization by skin contact. Exposure may result in irritation of skin, eyes, and mucous membranes. This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases. See Section 11 Toxicological Information for more detailed health information.
<b>Potential Environmental Effects</b>	Not available

## Section 2 Hazards Identification (Continued)

<b>Product Hazard Classifications</b>	<b>Meets Hazardous Criteria for Preparation/Mixture</b>		
	<b>EU:</b> Xi;R43	<b>WHMIS:</b> Exempt	<b>US OSHA:</b> Hazardous

## Section 3 Composition and Information on Ingredients

Hazardous Ingredients:				Hazard Classification of Pure Ingredients		
Chemical Name	CAS #	EINECS #	% by wt.	<u>EU</u>	<u>WHMIS</u>	<u>US OSHA</u>
Tris(hydroxymethyl)-aminomethane	77-86-1	2010644	< 2	Xi;R36/37/38	D2B	Irritant
ProClin* 300	Not available	Not available	< 0.6	C;R34-43-20/21/22 N;R51/53	D2B	Corrosive Sensitizer

See Section 15 Regulatory Information for additional information on hazard classifications.

See Section 16 for Risk Phrases and WHMIS Classification Description.

## Section 4 First Aid Measures

<b>Inhalation</b>	If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.
<b>Eye Contact</b>	If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.
<b>Skin Contact</b>	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.
<b>Ingestion</b>	If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

## Section 5 Fire Fighting Measures

<b>Flammable Properties</b>	Nonflammable aqueous solution.
<b>Extinguishing Media</b>	Use extinguishing media suitable for surrounding fire.
<b>Special Fire and Explosion Hazards</b>	No special hazards determined.
<b>Hazardous Combustion Products</b>	No combustion products posing significant hazards are expected from this product (an aqueous solution).
<b>Protective Equipment for Firefighters</b>	Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

## Section 6 Accidental Release Measures

<b>Personal Precautions</b>	This product contains material of animal origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed during clean up procedures.
<b>Spill and Leak Procedures</b>	As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
<b>Environmental Precautions</b>	Contain spill to prevent migration.

## Section 7 Handling and Storage

<b>Handling Precautions</b>	This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.
<b>Recommended Storage Conditions</b>	Keep away from incompatible material (see Section 10). To maintain efficacy, store according to the instructions in the product labeling.

## Section 8 Exposure Controls and Personal Protection

<b>Exposure Limits</b>	
<b>US OSHA:</b>	None established
<b>ACGIH:</b>	None established
<b>DFG MAK:</b>	None established
<b>NIOSH</b>	None established
<b>Japan</b>	None established
<b>Engineering Controls</b>	No special engineering controls are required. Use with good general ventilation.
<b>Respiratory Protection</b>	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.
<b>Eye Protection</b>	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
<b>Skin Protection</b>	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

## Section 9 Physical and Chemical Properties

<b>Physical State</b>	Liquid
<b>Color</b>	Colorless

### Section 9 Physical and Chemical Properties (Continued)

<b>Transparency</b>	Clear
<b>Odor</b>	Odorless
<b>Odor Threshold</b>	Not applicable
<b>pH</b>	8
<b>Freezing Point</b>	Not available
<b>Boiling Point</b>	Not available
<b>Flash Point</b>	Not applicable
<b>Evaporation Rate</b>	Not available
<b>Flammability (Solid, Gas)</b>	Not applicable
<b>Flammable Limits</b>	Not available
<b>Vapor Pressure</b>	Not available
<b>Vapor Density</b>	Not available
<b>Specific Gravity</b>	≈ 1 @20°C
<b>Solubility</b>	
<b>Water</b>	Miscible
<b>Organic</b>	Not available
<b>Coefficient of Water/Oil Distribution</b>	Not available
<b>Autoignition Temp.</b>	Not applicable
<b>Decomposition Temperature</b>	Not available
<b>Percent Volatiles</b>	Not available

### Section 10 Stability and Reactivity

<b>Stability</b>	Stable under normal temperatures and pressures.
<b>Hazardous Incompatibilities</b>	<p>Strong acids            Strong bases            Strong oxidizers            Metals and metallic compounds</p> <p>Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide &lt;0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.</p>

## Section 10 Stability and Reactivity (Continued)

<b>Hazardous Decomposition Products</b>	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).
<b>Conditions to Avoid</b>	Avoid contact with incompatible materials.

## Section 11 Toxicological Information

### Toxicity Data for Hazardous Ingredients

Tris(hydroxymethyl)-aminomethane

Oral LD50 Rat 5900 mg/kg

### Primary Routes of Exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

### Potential Effects of Acute Exposure

Exposure to ProClin 300 may result in irritation of skin, eyes and mucous membranes. Skin contact may result in possible sensitization. Eye contact may cause clouding of the cornea. Ingestion may cause gastrointestinal irritation; large doses given to animals resulted in collapse and coma.

Exposure to TRIS may result in irritation of skin, eyes and mucous membrane. Eye contact may result in redness, pain and corneal injury. Inhalation may result in chest pain and tightness, coughing, and difficult breathing. Ingestion may cause gastrointestinal irritation with burns to mouth and stomach, and large doses may cause weakness, collapse and death in laboratory animals.

This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.

### Potential Effects of Chronic Exposure

Frequent or long-term exposure may result in conjunctivitis and dermatitis.

### Symptoms of Overexposure

Symptoms of overexposure may include: throat irritation and coughing; dry, red, cracked skin; red irritated eyes; headache, drowsiness, dizziness, stupor; convulsions and coma.

### Carcinogenicity

This product does not contain a reportable concentration ( $\geq 0.1\%$ ) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.

### Other Effects

None identified.

### Conditions Aggravated by Exposure

None identified.

## Section 12 Ecological Information

<b>Ecotoxicity</b>	No information available.
<b>Biodegradability</b>	No information available.
<b>Bioaccumulation</b>	No information available.
<b>Mobility</b>	No information available.
<b>Other Adverse Effects</b>	No information available.

## Section 13 Disposal Considerations

### Waste Disposal

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

## Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

## Section 15 Regulatory Information

### US Federal and State Regulations

#### SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA.  
 Propylene Oxide is subject to reporting requirements of Section 313, Title III of SARA.  
 1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA.  
 Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA.  
 Zinc Chloride is subject to reporting requirements of Section 313, Title III of SARA.

#### CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.  
 Propylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Sodium Phosphate, Dibasic is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.

#### California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:  
**WARNING:** This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Propylene Oxide has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:  
**WARNING:** This product contains a chemical known to the State of California to cause cancer.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:  
**WARNING:** This product contains a chemical known to the State of California to cause cancer.

**Section 15 Regulatory Information (Continued)**

**Massachusetts MSL**  
 Ethylene Oxide is listed.  
 Propylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Butylated Hydroxytoluene is listed.  
 Sodium Phosphate, Dibasic is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.

**New Jersey Dept. of Health RTK List**  
 Ethylene Oxide is listed.  
 Propylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Butylated Hydroxytoluene is listed.  
 Sodium Phosphate, Dibasic is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.

**Pennsylvania RTK**  
 Ethylene Oxide is listed.  
 Propylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Butylated Hydroxytoluene is listed.  
 Sodium Phosphate, Dibasic is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.  
 Dipropylene Glycol is listed.

**EU Labeling Classification**

Classification	Risk and Safety Phrases
Irritant	R43 May cause sensitization by skin contact. S37 Wear suitable gloves. S28 After contact with skin, wash immediately with plenty of soap and water.

**Canada**

This product is exempt from WHMIS label and SDS requirements.

**PIN:** Not applicable

**Ingredients on Ingredient Disclosure List:**  
 Ethylene Oxide  
 Propylene Oxide  
 1,4-Dioxane  
 Butylated Hydroxytoluene  
 Zinc Chloride  
 Sodium Azide

**Ingredients with unknown toxicological properties:** Product is exempt

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.



## Section 16 Other Information

<b>Beckman Coulter Safety Rating</b>	<b>Flammability (Section V): 0</b> <b>Health (Section XI): 2</b> <b>Reactivity with Water (Section X): 0</b> <b>Contact (Section VIII): 2</b>	<b>Code</b> 0=none 1=slight 2=caution 3=severe
<b>Risk Phrases and WHMIS Classification Description From Section 3</b>	R20/21/22 Harmful by inhalation, in contact with skin and if swallowed. R34 Causes burns. R36/37/38 Irritating to eyes, respiratory system and skin. R43 May cause sensitization by skin contact. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in aquatic environment. D2B - Poisonous and Infectious Material: Division 2 - Other Toxic Effects: Toxic (Skin sensitization) D2B - Poisonous and Infectious Material: Division 2 - Other Toxic Effects: Toxic (Skin or Eye Irritation)	
* ProClin is a trademark of the Rohm and Haas Company.		
This SDS complies with EC Regulation 1907/2006 (REACH)		
For further information, please contact your local Beckman Coulter representative.		

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Printed in U.S.A.

**SAFETY DATA SHEET**

PTH

Doc. ID: A16972-75 AD

Revised (year/month/day) 2010/11/25

**Section 1 Company and Product Identification**

<b>Product Name</b>	Conjugate (Compartment R1c)
<b>Part Number</b>	Component of P/N A16972
<b>Product Use</b>	For In Vitro Diagnostic Use. See product literature for details.
<b>Series Name</b>	ACCESS®
<b>Manufacturer</b>	Beckman Coulter, Inc. 250 S. Kraemer Blvd Brea, CA 92821, U.S.A. Tel: 800-854-3633 <b>E-mail:</b> SDSNT@beckman.com
<b>EC REP Address</b>	Beckman Coulter Ireland Inc. Mervue Business Park Mervue, Galway, Ireland Tel: 353 91 774068
<b>Distributor and Emergency Phone No.</b>	 Refer to attached list, Document ID: <a href="#">472050</a> , for local distributor and emergency phone numbers.

**Section 2 Hazards Identification**

<b>Emergency Overview</b>	<p><b>Colorless; Clear; Liquid; Odorless</b></p> <p><b>Nonflammable aqueous solution.</b></p> <p><b>May cause sensitization by skin contact.</b></p> <p><b>Skin, eye and respiratory tract irritant.</b></p> <p><b>Contains material of animal origin.</b></p>
<b>Physical Hazards</b>	Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide <0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.
<b>Potential Health Effects Summary</b>	May cause sensitization by skin contact. Exposure may result in irritation of skin, eyes, and mucous membranes. This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases. See Section 11 Toxicological Information for more detailed health information.
<b>Potential Environmental Effects</b>	Not available

## Section 2 Hazards Identification (Continued)

<b>Product Hazard Classifications</b>	<b>Meets Hazardous Criteria for Preparation/Mixture</b>		
	<b>EU:</b> Xi;R43	<b>WHMIS:</b> Exempt	<b>US OSHA:</b> Not applicable

## Section 3 Composition and Information on Ingredients

Hazardous Ingredients:				Hazard Classification of Pure Ingredients		
Chemical Name	CAS #	EINECS #	% by wt.	<u>EU</u>	<u>WHMIS</u>	<u>US OSHA</u>
ProClin* 300	Not available	Not available	< 0.6	C;R34-43-20/21/22 N;R51/53	D2B	Corrosive Sensitizer

See Section 15 Regulatory Information for additional information on hazard classifications.  
 See Section 16 for Risk Phrases and WHMIS Classification Description.

## Section 4 First Aid Measures

<b>Inhalation</b>	If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.
<b>Eye Contact</b>	If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.
<b>Skin Contact</b>	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occur, obtain medical attention.
<b>Ingestion</b>	If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

## Section 5 Fire Fighting Measures

<b>Flammable Properties</b>	Nonflammable aqueous solution.
<b>Extinguishing Media</b>	Use extinguishing media suitable for surrounding fire.
<b>Special Fire and Explosion Hazards</b>	No special hazards determined.
<b>Hazardous Combustion Products</b>	No combustion products posing significant hazards are expected from this product (an aqueous solution).
<b>Protective Equipment for Firefighters</b>	Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

## Section 6 Accidental Release Measures

<b>Personal Precautions</b>	This product contains material of animal origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed during clean up procedures.
<b>Spill and Leak Procedures</b>	As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.
<b>Environmental Precautions</b>	Contain spill to prevent migration.

## Section 7 Handling and Storage

<b>Handling Precautions</b>	This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.
<b>Recommended Storage Conditions</b>	Keep away from incompatible material (see Section 10). To maintain efficacy, store according to the instructions in the product labeling.

## Section 8 Exposure Controls and Personal Protection

<b>Exposure Limits</b>	
<b>US OSHA:</b>	None established
<b>ACGIH:</b>	None established
<b>DFG MAK:</b>	None established
<b>NIOSH</b>	None established
<b>Japan</b>	None established
<b>Engineering Controls</b>	No special engineering controls are required. Use with good general ventilation.
<b>Respiratory Protection</b>	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.
<b>Eye Protection</b>	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
<b>Skin Protection</b>	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

## Section 9 Physical and Chemical Properties

<b>Physical State</b>	Liquid
<b>Color</b>	Colorless

## Section 9 Physical and Chemical Properties (Continued)

<b>Transparency</b>	Clear
<b>Odor</b>	Odorless
<b>Odor Threshold</b>	Not applicable
<b>pH</b>	7
<b>Freezing Point</b>	Not available
<b>Boiling Point</b>	Not available
<b>Flash Point</b>	Not applicable
<b>Evaporation Rate</b>	Not available
<b>Flammability (Solid, Gas)</b>	Not applicable
<b>Flammable Limits</b>	Not available
<b>Vapor Pressure</b>	Not available
<b>Vapor Density</b>	Not available
<b>Specific Gravity</b>	≈ 1 @20°C
<b>Solubility</b>	
<b>Water</b>	Miscible
<b>Organic</b>	Not available
<b>Coefficient of Water/Oil Distribution</b>	Not available
<b>Autoignition Temp.</b>	Not applicable
<b>Decomposition Temperature</b>	Not available
<b>Percent Volatiles</b>	Not available

## Section 10 Stability and Reactivity

<b>Stability</b>	Stable under normal temperatures and pressures.
<b>Hazardous Incompatibilities</b>	<p>Strong acids</p> <p>Strong bases</p> <p>Strong oxidizers</p> <p>Metals and metallic compounds</p> <p>Sodium azide forms explosive compounds with heavy metals. This product contains concentrations of azide &lt;0.1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.</p>

## Section 10 Stability and Reactivity (Continued)

<b>Hazardous Decomposition Products</b>	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).
<b>Conditions to Avoid</b>	Avoid contact with incompatible materials.

## Section 11 Toxicological Information

<b>Toxicity Data for Hazardous Ingredients</b>	Not applicable
<b>Primary Routes of Exposure</b>	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
<b>Potential Effects of Acute Exposure</b>	Exposure to ProClin 300 may result in irritation of skin, eyes and mucous membranes. Skin contact may result in possible sensitization. Eye contact may cause clouding of the cornea. Ingestion may cause gastrointestinal irritation; large doses given to animals resulted in collapse and coma.  This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases.
<b>Potential Effects of Chronic Exposure</b>	Frequent or long-term eye and skin exposure to ProClin 300 may result in conjunctivitis and dermatitis.
<b>Symptoms of Overexposure</b>	Symptoms may include: coughing, headache, fatigue, nausea, vomiting, dizziness, blurred vision, red and watery eyes, abdominal pain and unconsciousness.
<b>Carcinogenicity</b>	This product does not contain a reportable concentration ( $\geq 0.1\%$ ) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 67/548/EEC Annex I.
<b>Other Effects</b>	None identified.
<b>Conditions Aggravated by Exposure</b>	None identified.

## Section 12 Ecological Information

<b>Ecotoxicity</b>	No information available.
<b>Biodegradability</b>	No information available.
<b>Bioaccumulation</b>	No information available.
<b>Mobility</b>	No information available.
<b>Other Adverse Effects</b>	No information available.

## Section 13 Disposal Considerations

### Waste Disposal

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).  
Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

## Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

## Section 15 Regulatory Information

### US Federal and State Regulations

#### SARA 313

Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA.  
Propylene Oxide is subject to reporting requirements of Section 313, Title III of SARA.  
1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA.  
Sodium Azide is subject to reporting requirements of Section 313, Title III of SARA.  
Zinc Chloride is subject to reporting requirements of Section 313, Title III of SARA.

#### CERCLA RG's, 40 CFR 302.4

Ethylene Oxide is listed.  
Propylene Oxide is listed.  
1,4-Dioxane is listed.  
Zinc Chloride is listed.  
Sodium Azide is listed.

#### California Proposition 65

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:  
**WARNING:** This product contains a chemical known to the State of California to cause cancer and reproductive harm.

Propylene Oxide has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:  
**WARNING:** This product contains a chemical known to the State of California to cause cancer.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm. Accordingly, Beckman Coulter advises you of the following warning:  
**WARNING:** This product contains a chemical known to the State of California to cause cancer.

**Section 15 Regulatory Information (Continued)**

**Massachusetts MSL**  
 Sucrose is listed.  
 Ethylene Oxide is listed.  
 Propylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Butylated Hydroxytoluene is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.

**New Jersey Dept. of Health RTK List**  
 Ethylene Oxide is listed.  
 Propylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Butylated Hydroxytoluene is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.

**Pennsylvania RTK**  
 Sucrose is listed.  
 Ethylene Oxide is listed.  
 Propylene Oxide is listed.  
 1,4-Dioxane is listed.  
 Butylated Hydroxytoluene is listed.  
 Zinc Chloride is listed.  
 Sodium Azide is listed.  
 Dipropylene Glycol is listed.

**EU Labeling Classification**

Classification	Risk and Safety Phrases
Irritant	R43 May cause sensitization by skin contact. S37 Wear suitable gloves. S28 After contact with skin, wash immediately with plenty of soap and water.

**Canada**

This product is exempt from WHMIS label and SDS requirements.

**PIN:** Not applicable

**Ingredients on Ingredient Disclosure List:**  
 Ethylene Oxide  
 Propylene Oxide  
 1,4-Dioxane  
 Butylated Hydroxytoluene  
 Zinc Chloride  
 Sodium Azide

**Ingredients with unknown toxicological properties:** Product is exempt

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.



## Section 16 Other Information

<b>Beckman Coulter Safety Rating</b>	<b>Flammability (Section V): 0</b> <b>Health (Section XI): 2</b> <b>Reactivity with Water (Section X): 0</b> <b>Contact (Section VIII): 2</b>	<b>Code</b> 0=none 1=slight 2=caution 3=severe
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