

1. Identification

Product identifier	Epi proColon PCR Mix
Other means of identification	
Product code	SDS0021US
Recommended use	Reagent for medical diagnosis.
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Company name	Epigenomics, Inc.
Address	11055 Flintkote Ave. Suite A San Diego, CA 92121
Telephone	1-240-747-7002
Fax	1-240-747-7052
Emergency phone number	For Hazardous Materials [or Dangerous Goods] Incident Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC 1-800-424-9300 / +1 703-527-3887 CCN 840878

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	None.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash thoroughly after handling.
Storage	None.
Disposal	None.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients**Mixtures**

Chemical name	CAS number	%
Tris-(hydroxymethyl)aminomet hane	77-86-1	1-<5

Composition comments	The specific chemical identity and/or exact percentage of component(s) have been withheld as a trade secret. Components not listed are either non-hazardous or are below reportable limits. All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.
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4. First-aid measures

Inhalation	In case of discomfort, move to fresh air.
Skin contact	Wash contact areas with soap and water.

Eye contact	Rinse with water. Get medical attention if irritation persists after washing.
Ingestion	Rinse mouth thoroughly. No harmful effects expected in amounts likely to be ingested by accident.
Most important symptoms/effects, acute and delayed	Dry skin.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Get medical attention if any discomfort continues.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	None known.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing should be worn when fighting chemical fires. Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	The product is non-combustible.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Avoid prolonged and repeated contact. Wear suitable protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Absorb spillage with non-combustible, absorbent material.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged and repeated contact. Avoid inhalation of vapors or mists. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Keep container closed.

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Provide adequate ventilation.
Individual protection measures, such as personal protective equipment	
Eye/face protection	If risk of splashing, wear safety goggles or face shield.
Skin protection	
Hand protection	Wear protective gloves. Suitable gloves can be recommended by the glove supplier.
Skin protection	
Other	Wear appropriate clothing to prevent repeated or prolonged skin contact.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards	When material is heated, wear gloves to protect against thermal burns.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Liquid.

Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	8.3
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not applicable.
Flammability limit - upper (%)	Not applicable.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable under the prescribed storage conditions.
Possibility of hazardous reactions	None known.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	No hazard in normal industrial use.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause respiratory irritation.
Skin contact	Prolonged contact may cause dryness of the skin.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	No harmful effects expected in amounts likely to be ingested by accident.

Symptoms related to the physical, chemical and toxicological characteristics
Dry skin.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Tris-(hydroxymethyl)aminomethane (CAS 77-86-1)		
Acute		
Dermal		
LD50	Rat	> 5000 mg/kg, 24 Hours

Components	Species	Test Results
Oral LD50	Rat	5900 mg/kg
Skin corrosion/irritation	Prolonged contact may cause dryness of the skin.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	This product is not expected to cause respiratory sensitization.	
Skin sensitization	Not a skin sensitizer.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Carcinogenicity	Not classified by IARC, ACGIH, NTP or OSHA.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
NTP Report on Carcinogens		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
Reproductive toxicity	Test data conclusive but not sufficient for classification.	
Specific target organ toxicity - single exposure	Test data conclusive but not sufficient for classification.	
Specific target organ toxicity - repeated exposure	Test data conclusive but not sufficient for classification.	
Aspiration hazard	Not an aspiration hazard.	
12. Ecological information		
Ecotoxicity	The product is not expected to be hazardous to the environment.	
Persistence and degradability	No data available.	
Bioaccumulative potential		
Partition coefficient n-octanol / water (log Kow)		
Tris-(hydroxymethyl)aminomethane (CAS 77-86-1)	-2.31 (20°C)	
Mobility in soil	This product is water soluble and may disperse in soil.	
Mobility in general	The product is water soluble and may spread in water systems.	
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	
13. Disposal considerations		
Disposal instructions	Dispose in accordance with all applicable regulations. Do not discharge into drains, water courses or onto the ground.	
Local disposal regulations	Dispose of in accordance with local regulations.	
Waste from residues / unused products	Dispose of in accordance with local regulations.	
Contaminated packaging	Since emptied containers retain product residue, follow label warnings even after container is emptied.	
14. Transport information		
DOT		
Not regulated as dangerous goods.		
IATA		
Not regulated as dangerous goods.		
IMDG		
Not regulated as dangerous goods.		
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.	

15. Regulatory information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Toxic Substances Control Act (TSCA)

This material is not listed on the US TSCA inventory, therefore it may only be used for TSCA exempt purposes: Medical diagnosis use.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 13-December-2012

Revision date 20-August-2019

Version # 05

Further information None known.

Disclaimer

This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment. Polymedco Cancer Diagnostic Products, LLC cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.