

SAFETY DATA SHEET



1. Identification

ColoHealth PCR Mix

Product identifier

Other means of identification

SDS0021US

Product code

Reagent for medical diagnosis.

Recommended use

None known.

Recommended restrictions

Manufacturer/Importer/Supplier/Distributor information

Company name

New Day Diagnostics, LLC

Address

6701 Baum Dr., Ste. 110

Knoxville, TN 37919

Telephone

1-865-299-6250

Fax

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.

4. First-aid measures

Inhalation

In case of discomfort, move to fresh air.

| | |
|---|---|
| Skin Contact | Wash contact areas, move to fresh air |
| 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 | 28-October-2024 |
| Version # | 06 |
| Further information | None known. |

Disclaimer

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