



## Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

Trade Name: Cyfra-21-1 Antigen  
Material. No.: A32340H  
Specification: A32340H

Version: 1.0  
Page: 1 of 5

Revision: 002  
Revision Date: 17 JUN 2015

### 1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY UNDERTAKING

Identification of the Substance or Preparation: Cyfra-21-1, Cytokeratin 19 Fragment, Low Cross-Reactivity (LCR), Calibrator Grade, Catalog # A32340H supplied in Phosphate Buffered Saline (PBS), pH 7.4.

REACH Registration No: Not Applicable

Use of the Substance/Preparation:

Identified Use(s): For *in vitro* laboratory use. For professional use only.

Company Undertaking Identification:

Meridian Life Science, Inc.  
5171 Wilfong Road  
Memphis, TN 38134 U.S.A.  
901-382-8716

E-Mail: [info@meridianlifescience.com](mailto:info@meridianlifescience.com)

EMERGENCY TELEPHONE: US – 1-800-424-9300  
International – 1-703-527-3887

### 2. HAZARDS IDENTIFICATION

Classification: Void

#### Information Pertaining to Special Dangers for Human and Environment:

This mixture does not require labeling, based on the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest version. This mixture is not classified as hazardous according to the EC Dangerous Preparations Directive (1999/45/EC) or EC 1272/2008 (CLP).

#### Classification System

The classification is in alignment with current EC (European Community) Directives. It is expanded with information from technical literature.

**Physical Hazards:** Not classified as a physical hazard.

**Health Hazard:** Not classified as a health hazard. Contains human sourced and/or potentially infectious components. Contains added constituents of animal origin.

**Environmental Hazard:** Not classified as environmental hazard.

**Precautionary Statements:** The chemical, physical and toxicological properties of this mixture have not been thoroughly characterized. Avoid contact with eyes and skin. Do not inhale. This mixture contains material of animal origin and should be considered as potentially capable of transmitting infectious disease.

#### Potential Health Effects:

Inhalation: No data available.

Eyes: No data available. Eye exposure may cause irritation, redness and watering.

Skin: No data available.

Ingestion: No data available.

Chronic Effects: No data available.

Target Organs: No data available.



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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Chemical Characterization (Hazardous Chemical Ingredients):

None

**Dangerous Components According to EC Criteria:** None

**Additional Information:** For wording of the listed risk phrases, refer to Section 16.

Cell line supernatant has tested non-reactive for HIV1, HIV2, HCV antibodies, HBsAg and HIV Ag. No test guarantees a product to be non-infectious. Therefore, all material derived from human fluids or tissues should be considered as potentially infectious. Contains added constituents of animal origin.

### 4. FIRST AID MEASURES

**In Case of Inhalation:** Remove from source of exposure. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

**In Case of Skin Contact:** Remove clothing that product has touched. Rinse skin for 15 minutes. Seek medical attention if irritation persists.

**In Case of Eye Contact:** Immediately flush with tepid water for 15 minutes. Remove contact lenses if worn. Obtain medical attention if redness or irritation persists.

**In Case of Ingestion:** Rinse mouth with water. Seek medical attention if signs of toxicity occur.

**Self-Protection of the First Aider:** Follow company specific safety procedures.

### 5. FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media:** Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.

**Extinguishing Media Which Must Not Be Used for Safety Reasons:** Unknown.

**Special Exposure Hazards Arising From the Substance or Preparation Itself, Combustion Products, Resulting Gases:** Dilute aqueous solution not considered a fire hazard.

**Special Protective Equipment for Fire-Fighters:** Fire fighters should wear NIOSH-approved or self-contained breathing apparatus and full protective gear.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** See Section 8.

**Environmental Precautions:** Follow proper disposal procedures. Keep contaminated washing water and dispose of appropriately. Do not allow to enter sewers/surface or ground water.

**Methods for Cleaning Up:** Absorb spill with inert material/absorbent. Decontaminate the spill site following standard procedures. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations per Section 13.



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### 7. HANDLING AND STORAGE

**Handling:** Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

**Storage:** Short-term store at 2–8°C. Long term store at -20°C. Avoid multiple/freeze thaw cycles. Store in original container.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Exposure Limit Values:

**Exposure controls:** This product is not expected to require special ventilation controls. Facilities storing or using this product should be equipped with an eyewash fountain.

#### Personal Protection Equipment:

Respiratory Protection: A respirator is not expected to be required under normal conditions of use.

Hand Protection: Wear chemical resistant protective gloves.

Eye Protection: Wear appropriate protective safety eye glasses or goggles.

Body Protection: Wear lab coat or other protective garments. Remove contaminated clothing promptly.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** Liquid

**Physical State:** Liquid

**Color:** Red

**Odor:** Odorless

Parameter	Value
pH (20°C):	7.3 – 7.5
Melting Point/Range (°C):	Not Available
Boiling Point/Range (°C):	Not Available
Flash Point (°C):	Not Applicable
Ignition Temperature (°C):	Not Applicable
Vapor Pressure (°C):	Not Available
Density (G/Cm <sup>3</sup> ):	Not Available
Bulk Density (Kg/M <sup>3</sup> ):	Not Available
Water Solubility (20°C In G/L):	Fully Miscible
Partition Coefficient	Not Available
N-Octanol/Water (Log Po/W):	Not Available
Viscosity, Dynamic (Mpa S):	Not Available
Dust Explosion Hazard:	Not Applicable



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### 10. STABILITY AND REACTIVITY

**Reactivity:** Unknown.

**Stability:** Stable under ordinary conditions of storage and use.

**Conditions to Avoid:** No decomposition if used and stored according to specifications.

**Materials to Avoid:** Avoid strong oxidizers, strong acids and bases, heavy metals and their salts.

**Hazardous Decomposition Products:** None expected under normal conditions of use.

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### 11. TOXICOLOGICAL INFORMATION

Routes of exposure may include inhalation, skin absorption, and eye and skin contact.

**Acute Toxicity:** No data available.

**Irritant and Corrosive Effects:** No data available.

**Sensitization:** No data available.

**Carcinogenicity:** No data available. None of the components in this product at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

**Mutagenicity:** No data available.

**Reproductive Effects:** No data available.

**Teratogenicity:** No data available.

**Additional Toxicological Information:** This product is not subject to classification, according to the calculation method of the General EC Classification Guidelines for preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects according to our experience and information available to us.

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### 12. ECOLOGICAL INFORMATION

**Ecotoxicity:** No data available.

**Mobility in Environmental Compartments:** No data available.

**Adsorption/Desorption:** No data available.

**Persistence and Degradability:** No data available.

**Physical- and Photo-Chemical Elimination:** No data available.

**Biodegradation:** No data available.

**Bioaccumulative Potential:** No data available.

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### 13. DISPOSAL CONSIDERATIONS

**Appropriate Disposal / Product:** Dispose of unused product, spilled substance and waste in accordance with all applicable federal, state, local and provincial environmental and waste regulations.



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### 14. TRANSPORT INFORMATION

**Land Transport (ADR/RID/GGVSE):** Not restricted. Not regulated as hazardous goods.

**Sea Transport (IMDG-Code/GGVSee):** Not restricted. Not regulated as hazardous goods.

**Air Transport (ICAO-IATA/DGR):** Not restricted. Not regulated as hazardous goods.

### 15. REGULATORY INFORMATION

#### EU Regulations:

**Chemical Safety Assessment:** Observe general laboratory safety regulations when handling chemicals.  
This product is not subject to identification regulations under EC Directives.

### 16. OTHER INFORMATION

#### Exposure Scenarios:

Routes of exposure may include inhalation, skin absorption, and eye and skin contact.

#### Exposure Controls:

Observe general laboratory safety regulations when handling chemicals. This product is not expected to require special ventilation controls. Facilities storing or using this product should be equipped with an eyewash fountain.

#### Personal Protection Equipment:

Respiratory Protection: A respirator is not expected to be required under normal conditions of use.

Hand Protection: Wear chemical resistant protective gloves.

Eye Protection: Wear appropriate protective safety eye glasses or goggles.

Body Protection: Wear lab coat or other protective garments. Remove contaminated clothing promptly.

This Safety Data Sheet (SDS) was prepared in accordance with the hazard criteria and content requirements of the EU Dangerous Substances Directive (67/548/EEC), Dangerous Preparations Directive (1999/45/EC), the Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) (EC) No 1907/2006 and EC 1272/2008 Classification, Labeling, Packaging (CLP). These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The information contained in this SDS is believed to be accurate but does not purport to be all inclusive and should be used only as a guide for experienced personnel. It is the responsibility of the user or supplier to determine the applicability of the data to the formulation of necessary safety precautions. Meridian Life Science, Inc. shall not be held liable for any damage resulting from the use of the above product or the information contained in this SDS.