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Version 2

Reviewed on 1.1.2024

1. Chemical and Company Identification

Product Name: Human IgG Fc Lateral Flow Dipstick Assay Kit

Product Use: Laboratory Use

Manufacturer/Supplier: Cytodiagnostics Inc., 5867 South Garnett Road, Tulsa, Oklahoma 74146 USA

Phone: (866) 344-3954

Web: www.cytodiagnostics-us.com

Information and Support: customer_service-us@cytodiagnostics.com

2. Hazards Identification

Classification of the substance or mixture:

Flammable solids (Category 1), H228 Short-term (acute) aquatic hazard (Category 3), H402

For the full text of the H-Statements mentioned in this Section, see Section 16.

GHS Label Elements and Precautionary Statements:

Pictogram Signal Word Danger Hazard statement(s) H228 Flammable solid. H402 Harmful to aquatic life. Precautionary statement(s) Keep away from heat, hot surfaces, sparks, open flames and other ignition P210 sources. No smoking. P240 Ground and bond container and receiving equipment. P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish. P501 Dispose of contents/ container to an approved waste disposal plant. Hazards not otherwise classified: None

3. Composition/Information on Ingredients

This product contains: Lateral flow assay dipsticks, 15mL of sample dilution buffer and 1.5mL of lateral flow buffer

Components:

Component 1: Octylphenol polyethoxyethanol, >= 0.1-1% (w/w), CAS# 9036-19-5 *Component 2:* Immunoglobulin, <0.02% (w/w), CAS# 9007-83-4 *Component 3:* Colloidal Gold, <0.02% (w/w), CAS# 7440-57-5



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Component 4: Sample Dilution Buffer – Phosphate Buffered Saline (non-hazardous) *Component 5:* Lateral Flow Running Buffer - Proprietary components (trade secret per 29 CFR 1910. 1200 (i) (1)) (non-hazardous)

4. First Aid Measures

In case of skin contact: In case of contact with skin, immediately remove contaminated clothing and wash extensively with soap and water and seek medical advice if symptoms occur.

In case of ingestion: If swallowed and person is conscious wash mouth with water, seek medical advice immediately.

In case of eye contact: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If case of inhalation: In case of accident by inhalation, remove to fresh air. If breathing becomes difficult seek medical advice. If not breathing, give artificial respiration.

Most important symptoms and effects, both acute and delayed The most important known symptoms and effects are described in the labeling (see section 2) and/or in section 11.

Immediate medical attention and special treatment needed: No data available

5. Fire Fighting Measures

Suitable extinguising media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Specific hazards arising from the substance or mixture:

Carbon oxides

Development of hazardous combustion gases or vapours possible in the event of fire.

Special protective equipment and precautions for fire-fighters:

Wear self-contained breathing apparatus if necessary.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid aerosols or dust formation. Avoid breathing vapours, mist or gas.

Methods and materials for containment and cleaning up:

Keep in a suitable closed container for disposal. Do not allow product to enter drains. For disposal see section 13.

7. Handling and Storage

Precautions for safe handling:

Avoid formation of aerosols and dust. Provide adequate exhaust ventilation at places where dust and aerosols may form.

Conditions for safe storage:

Tightly closed. Dry. Keep away from oxidizing agents, strongly alkaline and strongly acid materials in order to avoid exothermic reactions.



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Recommended storage temperature 2-8°C

8. Exposure Controls/Personal Protection

Appropriate engineering controls: Standard industrial hygiene practice.

Body protection: The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Respiratory protection: Respiratory protection not required. In case of insufficient ventilation or for nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respiratory cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Eye protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

9. Physical and Chemical Properties

Appearance : Liquid Solutions	Physical s	state: Solid White Membrane and Clear, Colourless
Odour		Odourless
Odour threshold	no data available	
рН		7-8
Melting Point/Freezing point		no data available
Initial boiling point/boiling range	no data available	
Flash point		no data available
Evaporation rate	no data available	
Flammability (solid; gas)		no data available
Lower flammable/explosive limit	no data available	
Upper flammable/explosive limit	no data available	
Vapour pressure	no data available	
Vapour density	no data available	
Relative density	no data available	
Solubility		no data available
Partition coefficient - n-octanol/water		no data available
Auto-ignition temperature		no data available
Decomposition temperature		no data available



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Viscosity

no data available

10. Stability and Reactivity

Reactivity: No data available

Chemical stability: Stable under recommended storage conditions

Possibility of hazardous reactions: no data available

Conditions to avoid: Temperatures below 0°C, exposure to sunlight

Materials to avoid:

Risk of ignition or formation of inflammable gases or vapours with: Oxidizing agents Bases Strong acids

Hazardous decomposition products: Hazardous decompositon products formed under fire conditions. – Oxides of phoshorus, Sodium oxides, Hydrogen chloride gas, Potassium oxides, carbon oxides Other decomposition products – no data available In the event of fire: see section 5

11. Toxicological Information

Acute Toxicity

Oral LD50 No data available

Inhalation LD50 No data available

Dermal LD50 No data available

Other information on acute toxicity No data available

Skin: No data available - May be harmful in contact with skin. *Ingestion*: No data available - May be harmful if ingested. *Eyes:* No data available - May be harmful in contact with eyes. *Inhalation*: No data available - May be harmful if inhaled. *Germ Cell Mutagenicity:* No data available

Carcinogenicity

IARC:

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH:

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by ACGIH.

Additional Information

Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.



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Components

Octylphenol polyethoxyethanol

Acute toxicity

LD50 Oral - Rat - 1,900 - 5,000 mg/kg Remarks: (External MSDS) Symptoms: Vomiting, Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract., Risk of aspiration upon vomiting., Aspiration may cause pulmonary edema and pneumonitis. Inhalation: No data available LD50 Dermal - Rabbit - > 3,000 mg/kg Remarks: (External MSDS)

Skin corrosion/irritation

Skin - Rabbit Result: irritating - 4 h (OECD Test Guideline 404) Remarks: The value is given in analogy to the following substances: 4-(1,1,3,3-tetramethylbutyl)phenol

Serious eye damage/eye irritation

Eyes - Rabbit Result: Risk of serious damage to eyes. (Draize Test) Remarks: Risk of corneal clouding.

Respiratory or skin sensitization

Sensitisation test: - Human Result: negative Remarks: (External MSDS) Patch test on human volunteers did not demonstrate sensitization properties.

Germ cell mutagenicity No data available

Carcinogenicity No data available

Reproductive toxicity

Ingestion of excessive amounts by pregnant animals resulted in maternal and fetal toxicity. Did not show teratogenic effects in animal experiments.

Specific target organ toxicity - single exposure

Acute oral toxicity - Vomiting, Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract., Risk of aspiration upon vomiting., Aspiration may cause pulmonary edema and pneumonitis.

Specific target organ toxicity - repeated exposure No data available

Aspiration hazard

No data available

12. Ecological Information

No data available

13. Disposal Considerations

Disposal: Consult a licensed waste disposal specialist for proper destruction. Observe all local, state and federal regulations.



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14. Transport Information

Hazard class: Not regulated for transportation.

Product identification number: Not determined

15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations and the safety data sheet contains all of the information required by those regulations.

16. Other Information

This product is for laboratory research purposes, not for diagnostic or therapeutic use in humans or animals.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Users should make independent decisions regarding completeness of the information based on all sources available Cytodiagnostics Inc. shall not be held liable for any damage resulting from handling or contact with the above product.