

Developed and Manufactured by:



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Material Safety Data Sheet

Conforms to regulation (EC) No 1907/2006 (REACH) and 29 CFR 1910.1200(g)

Ref: T5008/30352

Issue Date: 2013-10

1. Identification of the substance / preparation and of the company / undertaking

1.1. Identification of the substance or preparation

Product Name: IBD-CHEK®
Cat. Number: T5008/30352
Composition: Conjugate
Diluent
Positive Control
Wash Solution
Stop Solution
Substrate
Microassay Plate

1.2. Use of the substance / preparation

An ELISA for the qualitative detection of elevated levels of lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation.

1.3. Company / undertaking identification

Manufactured by:
TECHLAB®, Inc.
2001 Kraft Drive
Blacksburg, VA 24060

Distributed by:
Alere North America, LLC.
30 South Keller Road
Orlando, Florida 32810

1.4. Emergency telephone: 1-800-222-1222 (Poison Control) or your local physician

2. Hazard Identification

Except for the Diluent and Wash Buffer Concentrate, all kit components have been classified as non-hazardous according to EC Directive 67/548 EC and 1999/45/EEC. Therefore, the information in this MSDS only applies to the Diluent and Wash Buffer Concentrate.

Once diluted to normal use concentration, the Diluent and Wash Buffer are classified as non-hazardous

Hazard description:
Harmful by inhalation, in contact with skin and if swallowed
Danger of cumulative effects.

The **Conjugate, Diluent** and **Microassay Plate** contain material of animal origin:
Animal proteins are potentially infectious

The **Positive Control** contains material of animal and human origin:
Animal proteins are potentially infectious

The **Positive Control** contains lactoferrin which is a human derived material. Material has been tested and found negative for antibody to HIV-1, HIV-2, HCV, and HbsAg. No known test method can offer complete assurance that infectious agents are absent. ALL HUMAN SOURCE PRODUCTS SHOULD BE HANDLED AS POTENTIALLY INFECTIOUS MATERIAL. A procedure for handling biohazards is published in the CDC/NIH *Manual of Biosafety in Microbiology & Biomedical Laboratories*.

3. Composition / information on ingredients

Product	Hazardous Chemicals	CAS No.	%	EC No.	Classification
Stop Solution	Sulfuric Acid	7664-93-9	2.89%	231-639-5	C; R35
20X Wash Buffer	Thimerosal	54-64-8	0.2%	200-210-4	T+, N; R 26/27/28-33-50/53
Conjugate	Animal proteins	N/A	N/A	N/A	N/A
10X Diluent	Thimerosal	54-64-8	0.2%	200-210-4	T+, N; R 26/27/28-33-50/53
Plate	Animal proteins	N/A	N/A	N/A	N/A
Positive Control	Animal/human proteins	N/A	N/A	N/A	N/A

For the wording of the listed risk phrases refer to section 16.

4. First Aid Measures

Symptoms of poisoning may occur even after several hours; therefore, medical observation for at least 48 hours after the accident is recommended.

- **After inhalation:** Remove person to fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **After skin contact:** Rinse immediately with water for 15 minutes. If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse open eye with water for 15 minutes under running water. Then consult doctor.
- **After swallowing:** Induce vomiting, only if person affected is fully conscious. Wash out mouth with water. Drink large quantities of water. Seek medical attention immediately.
- **The following symptoms may occur:**
Headache, cramps, dizziness, nausea, diarrhea.

5. Fire Fighting Measures

- **Suitable extinguishing agents:**
Product itself does not burn. Use fire fighting measures that suit the environment.
- **Special hazards caused by the material, its products of combustion or flue gases:**
Formation of mercury fumes possible.
- **Protective equipment:**
No special measures required. In case of burning of a larger amount: Wear breathing equipment and protective suit to avoid contact with skin and eyes.

6. Accidental Release Measures

- **Person-related safety precautions:**
Do not inhale vapors. Prevent contact with skin and eyes.
 - **Measures for environmental protection:**
Do not allow product to reach sewage system or water bodies.
 - **Measures for cleaning / collecting:**
Ensure adequate ventilation. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to item 13.
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7. Handling and Storage

7.1. Handling

- **Information for safe handling:**
Open and handle container with care. Prevent formation of aerosols.
- **Information about protection against explosions and fires:**
In cases of fire formation of dangerous fumes possible.

7.2. Storage

- **Requirements to be met by storerooms and containers:**
No special requirements.
- **Information about storage in one common storage facility:**
Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store refrigerated (2-8 °C).
- **Storage class:**
Not inflammable liquids – storage according to the national regulations.

7.3. Specific Use(s): N/A

8. Exposure Controls and Personal Protection

8.1. Exposure limit values

Not available for this preparation.

8.2. Exposure controls

8.2.1. Occupational exposure controls

8.2.1.1. Respiratory protection
Not required

8.2.1.2. Hand protection
Compatible chemical-resistant gloves.
For the selection of glove material, breakthrough times and other test results are not available for this specific preparation.

8.2.1.3. Eye protection
Safety goggles.

- 8.2.1.4. Skin protection**
Protective work clothing.

- 8.2.2. Environmental exposure controls**
Observe national regulations for the disposal of mercury containing preparations.
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9. Physical and Chemical Properties

- **General information**
Form: Liquid preparations
Color: Various
Smell: Characteristic
 - **Important health, safety and environmental information**
Melting point/Melting range: N/A
Boiling point/Boiling range: N/A
Flash point: N/A
Self-inflammability: Not self-inflammable
Danger of explosion: Not explosive
Solubility in/Miscibility with water: Fully miscible
pH-value: N/A
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10. Stability and Reactivity:

- **Conditions to be avoided:**
No decomposition if used according to specifications.
 - **Materials to avoid:**
Do not put into iron containers. Do not mix with magnesium, ammonia, acetylene, hydroxylamine, phosphates, copper, antimony, acids, arsenic, or sulfites.
Hazardous Polymerization: None
 - **Hazardous decomposition products:** N/A
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11. Toxicological Information

Acute toxicity

LD/LC50 values that are relevant for classification

54-64-8 Thimerosal

Oral, rat: LD50: 75 mg/kg

Target Organs: Central nervous system, kidneys, skin, eyes, and respiratory tract

Primary Routes of Entry: Inhalation, ingestion, skin or eye contact

Primary irritant effect

On the skin: Irritant for skin and mucous membranes.

On the eye: Irritant effect.

Sensitization: Allergic reactions possible.

Subacute to chronic toxicity: Danger of cumulative effects.

Additional toxicological information:

Danger by skin resorption.

For organic mercury compounds the following effects are found:

Prolonged exposure can cause disorders/damage of the nervous system.

Pregnant women should not come in direct contact with this product.
The product shows the following dangers according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:
Harmful.

12. Ecological Information

12.1. Ecotoxicological effects

Toxic for aquatic organisms.

Long lasting damaging effect on stretches of water possible.

Water hazard class 2 (Self assessment): hazardous for water. Adverse effects in the environment cannot be excluded when product is not handled or disposed of in an appropriate way.

Do not allow product to reach ground water, water bodies or sewage system.

12.2. Mobility

N/A

12.3. Persistence and degradability

Readily degradable = no

12.4. Bioaccumulative potential

Log Pow = N/A

BCF = N/A

12.5. Other adverse effects

N/A

13. Disposal Considerations

- **Product**

Recommendation:

Must not be disposed of together with household garbage.

Do not allow product to reach sewage system.

Residues of chemicals and preparations are generally considered hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies, which will give advice on how to dispose of hazardous waste.

- **Uncleaned packagings**

Recommendation: Disposal must be made according to official regulations.

Recommended cleaning agent: Water, if necessary with cleaning agent.

14. Transport Information

- **Land transport ADR / RID and GGVS / GGVE (cross-border/domestic)**

ADR / RID-GGV / E Class: N/A

- **Maritime transport IMDG / GGVSea**

IMDG/ GGVSea Class: N/A

Marine pollutant: Yes

- **Air Transport ICAO-TI and IATA-DGR**

ICAO / IATA Class: N/A

- **Transport / Additional information:**
Because of small volumes no classification as dangerous goods according to above regulations.
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15. Regulatory Information

- **Designation according to EC guidelines:**
The product has been classified and labeled in accordance with EC Directives / Ordinance on Hazardous Materials.

Code letter and hazard designation of product:

Xn 
Xn Harmful.

Hazard-determining components of labeling:

Thimerosal.

Risk phrases:

20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
33 Danger of cumulative effects.

Safety phrases:

13 Keep away from food, drink and animal feeding stuffs
28 After contact with skin, wash immediately with plenty of water
36 Wear suitable protective clothing
45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
60 This material and this container must be disposed of as hazardous waste
61 Avoid release to the environment. Refer to special instructions / safety data sheets

- **National regulations:**
Please ask your national/regional authorities.
 - **Water hazard class:**
Water hazard class 2 (Self-assessment): hazardous for water.
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16. Other Information

The above information and recommendations are believed to be correct as of the date of this Material Safety Data Sheet but shall not be taken to be all-inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. TECHLAB[®], Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.

Ingredients of animal origin are sourced from countries/areas with no-risk or low-risk status for bovine spongiform encephalopathy (BSE).

- **Relevant R-phrases:**

20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

26/27/28 Very toxic by inhalation, in contact with skin and if swallowed.

33 Danger of cumulative effects.

35 Causes severe burns.

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **Abbreviations:**

N/A = not applicable

Effective: 10/2013

Replaces version from: 10/2011

Modification versus previous version: Change in distributor information and update animal origin statement.

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