

**SECTION 1: IDENTIFICATION****Product Identifier****Product Name:** LEUKO EZ VUE®**Product Code:** 5019MC, D4, 5018P**Cat. Number:** T30355**Other means of identification:** This SDS is for a medical *in vitro* diagnostic (IVD) kit. The D4 component has hazards associated with it, refer to the corresponding component SDS for more information. 5019MC and 5018P are not classified as hazardous.**Intended Use of the Product**

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

Name, Address, and Telephone of the Responsible Party**Company, Manufacturer**TECHLAB, Inc.
2001 Kraft Drive
Blacksburg, VA 24060**Distributed by:**Alere North America, LLC
30 South Keller Road
Orlando, Florida 32810 USA**Emergency Telephone Number****Emergency Number** : + (207) 730-5750**SECTION 2: HAZARDS IDENTIFICATION****Classification of the Substance or Mixture****Classification (GHS-US)**

Skin Sens. 1 H317

Full text of H-phrases: see section 16

Label Elements**GHS-US Labeling****Hazard Pictograms (GHS-US)**

:



GHS07

Signal Word (GHS-US)

: Warning

Hazard Statements (GHS-US)

: H317 - May cause an allergic skin reaction.

Precautionary Statements (GHS-US): P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.**Other Hazards**

No additional information available

Unknown Acute Toxicity (GHS-US) Not available**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

Refer to component Safety Data Sheets

SECTION 4: FIRST AID MEASURES

Refer to component Safety Data Sheets

LEUKO EZ VUE®

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SECTION 5: FIRE-FIGHTING MEASURES

Refer to component Safety Data Sheets

SECTION 6: ACCIDENTAL RELEASE MEASURES

Refer to component Safety Data Sheets

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling Refer to component Safety Data Sheets

Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store closed in a dry, cool and well-ventilated place. Store refrigerated (2 - 30 °C)

Specific End Use(s)

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

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Refer to component Safety Data Sheets

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Refer to component Safety Data Sheets

SECTION 10: STABILITY AND REACTIVITY

Refer to component Safety Data Sheets

SECTION 11: TOXICOLOGICAL INFORMATION

Refer to component Safety Data Sheets

SECTION 12: ECOLOGICAL INFORMATION

Refer to component Safety Data Sheets

SECTION 13: DISPOSAL CONSIDERATIONS

Refer to component Safety Data Sheets

SECTION 14: TRANSPORT INFORMATION

In Accordance with DOT Not regulated for transport

In Accordance with IMDG Not regulated for transport

In Accordance with IATA Not regulated for transport

In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

US Federal Regulations

LEUKO EZ VUE®

SARA Section 311/312 Hazard Classes

Immediate (acute) health hazard

US State Regulations

Refer to component Safety Data Sheets

Canadian Regulations

LEUKO EZ VUE®

WHMIS Classification

Class D Division 2 Subdivision B - Toxic material causing other toxic effects



This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 03/17/2016

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

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|-----------------------|-------------------|--------------------------------------|
| Kit Components | Membrane Cassette | No known OSHA/WHMIS hazards |
| | Diluent | May cause an allergic skin reaction. |
| | Positive Control | No known OSHA/WHMIS hazards |

GHS Full Text Phrases:

| | |
|--------------|-------------------------------------|
| Skin Sens. 1 | Skin sensitization Category 1 |
| H317 | May cause an allergic skin reaction |

Party Responsible for the Preparation of This Document

TECHLAB, Inc
2001 Kraft Drive
Blacksburg, VA 24060

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS