

Revised (year/month/day) 2012/07/13

**Product Information** 

**Product Name** Hema Screen™ Fecal Occult Blood Test

Part Number HS-50; HS-100; HS-34; HS-1000; HSER-50; HSER-100; HSTAT-50; HSPP-50; HSEZ-

50; HSDV-8; HSDV-15ML

Series Name Hema Screen™

## Components

Hema Screen™ Developer; Hema Screen™ Guaiac Slide

#### **Transportation Information**

Tech Entry NOS Shipping Nm: ETHANOL, HYDROGEN PEROXIDE

Multiple KIT Number: 0

#### Detail DOT Information

DOT Proper Shipping Name: ETHANOL OR ETHYL ALCOHOL/ETHANOL OR ETHYL ALCOHOL SOLUTIONS

UN ID Num: UN1170

DOT Packaging Group:

Hazard Class/Label: 3- FLAMMABLE LIQUID/CORROSIVE

Subsidiary Risk: None

Non Bulk Pack/Bulk Pack: 202/242

Vessel Stow Req.:

NAERG Number: 127

Packaging Exception/Special Provisions: 150/173.150

## Detail IATA Information

IATA UN ID Num: 1170

IATA Proper Shipping Name: ETHANOL SOLUTION

UN Packing Group:

IATA UN Class/Label: 3- FLAMMABLE LIQUID/CORROSIVE

Subsidiary Risk: None

Packaging Note Cargo: 307

IATA ERG Code: 3L

Special Provisions/Exceptions: A3, A58

#### IMDG

Hazard Class: 3- FLAMMABLE LIQUID/CORROSIVE

Subsidiary Risk: None

Special Provisions/Exceptions: 274

Marine Pollutant No

#### Canadian TDG

IATA UN ID Num: 3- FLAMMABLE LIQUID/CORROSIVE

Subsidiary Risk: None

Special Provisions/Exceptions: 16





Fecal Occult Blood Test, *FOBT* (Hema Screen™)

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Complies with 91/155/EEC, 1907/2006 (REACH) and amendments, OSHA's Hazard Communication Standard, 29 CFR 1910.1200; and the requirements of the U.S. Department of Labor Occupational Safety & Health Administration.

#### **SECTION 1: PRODUCT IDENTIFICATION**

**PRODUCT NAME:** Hema Screen™ Fecal Occult Blood Test (*DEVELOPER*) **SERIES NAME:** Hema Screen™

**CATALOGUE No.:** HS-50; HS-100; HS-34; HS-1000; HSER-50; HSER-100; HSTAT-50; HSPP-50; HSEZ-50; HSDV-8; HSDV-15ML

**PRODUCT USE:** For In Vitro Diagnostic Use. See product literature for details.

**MANUFACTURER:** Immunostics, Inc. Telephone: +1 (732) 918-0770 Toll Free: +1 (800) 722-7505

1750 Brielle Ave. Emergency: +1 (800) 424-9300 Int'l: +1 (703) 527-3887

Suite A5 Fax: +1 (732) 918-0618
Ocean, NJ 07712 Fmail: Technical@lmmun

Email: <u>Technical@Immunostics.com</u>
Website: www.Immunostics.com

#### **SECTION 2: COMPOSITION**

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	IUPAC	SYNONYMS	MOLECULAR FORMULA	IDENTIFIERS	
Water	Oxidane	Hydrogen oxide, Dihydrogen monoxide, Hydrogen monoxide, Dihydrogen oxide & Hydrogen hydroxide	H₂O	CAS PUBCHEM EC UN RTEC	7732-18-5 962 231-791-2 N/A ZC0110000
Guaiac		guaiac resin, guaiacum spp., guaiacum (resin), gum guaiac, gum guaiacum	N/A	CAS PUBCHEM EC UN RTEC	9000-29-7 N/A 232-535-2 N/A ME6260000
Hydrogen Peroxide IMIS: 1470	Dihydrogen Dioxide	Dioxidane	H <sub>2</sub> O <sub>2</sub> (IARC) carcinogenic classification: Group 3-not classifiable as to its carcinogenicity to humans.	CAS PUBCHEM EC UN RTEC	7722-84-1 784 231-765-0 2984 <sup>1</sup> MX0887000
Ethyl Alcohol IMIS: 1060	Ethanol	Ethyl alcohol, Ethyl hydrate, Ethyl hydroxide, Ethylic alcohol, Ethylol, Hydroxyethane, Methyl Carbinol	C <sub>2</sub> H <sub>6</sub> O (IARC) carcinogenic classification: Group 3-not classifiable as to its carcinogenicity to humans.	CAS PUBCHEM EC UN RTEC	64-17-5 702 200-578-6 1170 KQ6300000

#### **SECTION 3: HAZARDOUS INGREDIENTS**

		OSHA PEL	ACGIH TLV	DFG MAK	NIOSH	Classification: 1999/45/EC & 67/548 EEC	
						Labeling	R & S Phrases
Hydrogen Peroxi	, ,	=			1 ppm; 1.4		R8; R34. <sup>2</sup>
EU Index: EU Classification:	008-003-00-9 Oxidant (O) Corrosive (C)	1 ppm TWA; 1.4 mg/m <sup>3</sup>	1 ppm TWA	1.4 mg/m <sup>3</sup> (I	mg/m³ TWA ( <b>IDLH</b> ): 75 ppm	OXIDIZER 5.1	S3; S26; S28; S36/37/39; S45. <sup>3</sup>
Ethanol		1000 ppm			1000 ppm;		
EU Index:	603-002-00-5	TWA;	1000 ppm; 1880 mg/m <sup>3</sup>	500 ppm,	1900 mg/m <sup>3</sup> TWA		R11; R20/21/22.5
EU Classification:	Highly Flammable	1900 mg/m <sup>3</sup> TWA	TWA <sup>4</sup>	960 mg/m³	(IDLH): 3,300 ppm [LEL]		S16; S36/37.6

<sup>&</sup>lt;sup>1</sup> 8-20% soln.

<sup>&</sup>lt;sup>6</sup> S16 Keep away from sources of ignition – No Smoking; S36/37 Wear suitable protective clothing and gloves.



<sup>&</sup>lt;sup>2</sup> R8 Contact with combustible material may cause fire; R34 Causes burns.

<sup>&</sup>lt;sup>3</sup> S3 Keep in a cool place; S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice; S28 After contact with skin, wash immediately with plenty of water; S36/37/39 Wear suitable protective clothing, gloves and eye/face protection; S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

<sup>&</sup>lt;sup>4</sup> American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV); Appendix A4 - Not Classifiable as a Human Carcinogen (Listed under Ethanol)

<sup>&</sup>lt;sup>5</sup> R11 Highly Flammable; R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.



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SECTION 4: FIRST AID MEASURES

EYES: If product is splashed in eyes, wash eyes under gently running water for 15 minutes or longer,

making sure that the eyelids are held open. Obtain medical attention.

**SKIN:** Flush contact area with cold water. Wash effected area with soap and water ... rinse thoroughly.

Skin that has been bleached white will return to normal color within a few hours. If irritation persists, contact

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a physician.

**INGESTION:** If fully conscious, lucid and not convulsing, victim should drink as much water as possible. Contact a physician or

poison control center immediately. Do not induce vomiting unless instructed to do so by a certified medical

authority.

INHALATION: Move victim into fresh air, If breathing is labored or victim loses consciousness contact a physician

immediately, If breathing stops, administer artificial respiration; use oxygen as required. Contact a physician

immediately.

**SECTION 5: FIRE & EXPLOSION HAZARD DATA** 

FLASH POINT: Hema Screen <sup>™</sup> Developer: 21 °C (69.8 °F)

Ethyl Alcohol 56 °F (13 °C) Tag Closed Cup

60 °F (16 °C) Tag Open Cup

Peroxide Not Combustible

Water N/A

**AUTOIGNITION TEMPERATURE:** N/A

HAZARD CLASSIFICATION:

**HEALTH:** 1<sup>7</sup> **FLAMMABILITY\*:** 2<sup>9</sup> **REACTIVITY:** 1<sup>10</sup> SPECIAL OX

**EXTINGUISHING MEDIA:** Use water, carbon dioxide, dry chemicals or universal-type foams applied as per

manufacturer's recommendations.

SPECIAL FIRE FIGHTING PROCEDURES: Wear protective clothing. Use self-contained breathing apparatus

(NIOSH Certified). Do not use oxidizable sorbents. Vapors form explosive mixtures with air. Vapors are heavier than air; fire may

flash from ignition source back along vapor trail.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Oxygen evolution from decomposition of hydrogen peroxide will

support combustion and may serve to intensify a fire. (Hydrogen Peroxide

concentration is nominal)

HAZARDOUS DECOMPOSITION PRODUCTS: N/A

SECTION 6: ACCIDENTAL RELEASE MEASURES

If material is released or spilled, wear all appropriate protective equipment described in Section 8 before cleaning up the spill or handling contaminated material. Wipe up the spill and dispose of the contaminated material. Avoid creating aerosols or dust while cleaning up a spill.

After the material has been picked up and contained in a bag, wash the spill site with distilled or deionized water.

Personal Precautions Use good laboratory procedures; avoid eye and skin contact.

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and

dispose according to local regulations.

Environmental Precautions Contain spill to prevent migration.

<sup>7</sup> Exposure would cause irritation with only minor residual injury (e.g., acetone)

<sup>8</sup> Flammability depends on the ratio of water and ethanol. The very *common* 95% aqueous ethanol has a flash point of 55°F.

M. Hristova, D. Damgaliev, D. Popova; Estimation of Water-Alcohol Mixture Flash Point; *Journal of the University of Chemical Technology and Metallurgy*, 45, 1, 2010, 19-24.

Must be moderately heated or exposed to relatively high ambient temperature before ignition can occur (e.g., diesel fuel has a flash point between 38°C (100°F) and 93°C (200°F)).

10 Normally stable, but can become unstable at elevated temperatures and pressures (e.g. propene)



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## **SECTION 7: HANDLING & STORAGE**

**HANDLING & STORAGE:** Store at room temperature (15°-30°C or 59°-86°F).

**OTHER PRECAUTIONS:** 

For in vitro diagnostic use. Do not substitute reagents from kits from other manufacturers. You may interchange slides & reagent from Immunostics hemascreen<sup>™</sup> kits as long as they are within the expiration date; except with the "Easy Readability" Product line. Patient specimens and all materials coming into contact with them should be handled as if capable of transmitting infections and disposed of with proper precautions. Replace bottle closure when Hema Screen<sup>™</sup> Developer is not being used. This will diminish alcohol vapors and reduce the risk of developer contamination. To maintain efficacy, store according to the instructions in the product labeling.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**VENTILATION:** Well Ventillated

RESPIRATORY PROTECTION: Under normal conditions, the use of this product should not require respiratory

protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional. Use a surgical mask or similar respiratory

protection to cover nose, mouth and mucous membranes.

EYE PROTECTION: Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29

CFR 1910.133, European Standard EN166 or appropriate government standards.

SKIN PROTECTION: Wear Impervious gloves, such as latex or equivalent, should be worn to prevent skin contact and

especially cover any cuts, abrasions or skin lesions. Dispose of gloves as biohazardous material. Wash hands thoroughly after removing gloves. Use extreme caution with any sharp object to avoid percutaneous exposure to material. Wear outer protective garments such as a lab coat or gown. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or

and coat of gown. Refer 0.3. OSTA 29 OFR 1910.130, European Standard EN374 (

appropriate government standards.

#### OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

## SECTION 9: PHYSICAL/CHEMICAL CHARACTERISTICS

Boiling Point: 78 °C-81 °C Freezing Point: < -20 °C Specific Gravity ( $H_20 = 1$ ): 0.86 @ 20 °C Vapor Pressure (mm Hg): 40 mm Hg @ 25 °C

Vapor Density (AIR = 1): 1.6

Evaporation Rate (Butyl Acetate = 1): 2.5

Solubility in Water: Completely Miscible

Appearance and Odor: Clear & Colorless liquid w/ Characteristic Alcohol Scent

#### **SECTION 10: STABILITY AND REACTIVITY**

STABILITY (3 yrs.): Is generally considered to be stable when stored according to approved labeling except when exposed

to excessive heat, sparks, open flame, other sources of ignition and incompatible chemicals.

CONDITIONS TO AVOID: Store at room temperature (15°-30°C or 59°-86°F). Do not refrigerate or freeze. Protect from

heat, humidity, and light, ignition sources & incompatible materials.

## **INCOMPATIBILITY (MATERIAL TO AVOID):**

Concentrated nitric and sulfuric acids, strong oxidizing agents. Excessive heat.

Rust, dirt, dust and inert particulate solids in general. Iron, copper and heavy metals, their salts and alloys. Ultra violet light may induce photo decomposition.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: NONE; When stored as labeled, no known hazardous

decomposition products are formed during the shelf-life of this

product.

HAZARDOUS POLYMERIZATION: NONE EXPECTED





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#### **SECTION 11: TOXICOLOGICAL INFORMATION**

#### TOXICOLOGICAL INFORMATION:

	Inhalation LC50 Rat	Oral LD50 Rat	Dermal LD50 Rat	Dermal LD50 Rabbit
Ethyl Alcohol	124.7 mg/L 4 h	7060 mg/kg	N/A	N/A
Hydrogen Peroxide	2 mg/L 4 h	801 mg/kg	4060 mg/kg	2000 mg/kg
Guaiac	N/A	N/A	N/A	N/A

Primary Routes of

Exposure

The most likely routes of exposure are skin and eye contact. Inhalation may occur if mists are formed in

product use.

Potential Effects of Acute Exposure May cause irritation or burning of skin and eyes by contact. Inhalation and ingestion of large volumes may cause burning of mucous membrane, respiratory irritation, and central nervous system depression.

Potential Effects of Chronic Exposure Chronic exposure may result in effects similar to those described for acute exposure. Frequent or long-term contact may dry out the skin resulting in dermatitis. Repeated exposure may result in allergic

reactions

Symptoms of Overexposure Symptoms of overexposure may include: throat irritation and coughing; dry, red, cracked skin; red

irritated eyes; headache, drowsiness, dizziness, stupor; and convulsions.

Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 67/548/EEC

Annex I.

Irritation/Sensitization

May cause sensitization by inhalation and skin contact.

Other Effects

None identified.

Conditions Aggravated by Exposure

Individuals with eye and skin disorders may find these conditions aggravated by exposure to this product. Individuals with eye, kidney, liver and cardiovascular, nervous and respiratory system disorders may find

these conditions aggravated by exposure to this product.

Mutagenicity

None identified.

Reproductive Toxicity

Reproductive effects have been reported in animal studies.

#### **SECTION 12: ECOLOGICAL INFORMATION**

**Ecotoxicity** 

Fresh Water Species Ethyl Alcohol Toxic to fish and other water organisms.

96 Hr LC50 Oncorhynchus mykiss: 12.0 - 16.0 mL/L [static]; 96 Hr LC50 Pimephales promelas: >100 mg/L [static]; 96 Hr LC50 Pimephales promelas: 13400 - 15100 mg/L

[flow-through]

Hydrogen Peroxide

96 Hr LC50 Pimephales promelas: 16.4 mg/L; 96 Hr LC50 Lepomis macrochirus: 18-56

mg/L [static]; 96 Hr LC50 Oncorhynchus mykiss: 10.0-32.0 mg/L [static]

Microtox Water Flea

No information available.

Ethyl Alcohol 48 Hr LC50 Daphnia magna: 9268 - 14221 mg/L; 24 Hr EC50 Daphnia magna: 10800

mg/L; 48 Hr EC50 Daphnia magna: 2 mg/L [Static]

Hydrogen Peroxide 24 Hr EC50 Daphnia magna: 7.7 mg/L; 48 Hr EC50 Daphnia magna: 18 - 32 mg/L

[Static] Fresh Water Algae

Hydrogen Peroxide

72 Hr EC50 Chlorella vulgaris: 2.5 mg/L

Biodegradability Bioaccumulation Mobility Other Adverse Effects No information available. No information available. No information available. No information available.

#### **SECTION 13: DISPOSAL CONSIDERATIONS**

WASTE DISPOSAL METHOD: Dispose of waste product, unused product and contaminated packaging in

compliance with federal, state and local regulations. If unsure of the applicable

requirements, contact the authorities for information.

WITH SPECIMEN: Patient specimens and all materials coming into contact with them should be handled

as if capable of transmitting infections and disposed of with proper precautions.

## **SECTION 14: TRANSPORT INFORMATION**



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International Shipping Information	IATA Hazard Class Subsidiary Risk Special Provisions IMDG Hazard Class Subsidiary Risk Special Provisions		3 None A112 3 None
	Special Provisions Marine Pollutant		274 No
US DOT	Hazard Class		3
	Subsidiary Risk		None
	Special Provisions		173.150; None
European ADR	Classification		3
	Classification Code		F1
	Subsidia	ary Risk	None
Canadian TDG	TDG Classification		3
	Subsidia	ary Risk	None
	Special	Provisions	16

ETHYL ALCOHOL:

Department of Transportation Regulation Number (49 CFR 172.101) and Guide: 1170 127

HYDROGEN PEROXIDE:

Department of Transportation Regulation Number (49 CFR 172.101): 2984 140 (8-20%

solution);

#### SECTION 15: REGULATORY INFORMATION

#### **U.S. FEDERAL REGULATIONS**

TSCA (TOXIC SUBSTANCE CONTROL ACT): None

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): None SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT): None

311/312 HAZARD CATEGORIES: None

313 REPORTABLE INGREDIENTS: Not Reportable

## **EU REGULATIONS**

WATER HAZARD CLASS (GERMANY): WGK 1, low water endangering

#### **CANADA**

THIS PRODUCT IS EXEMPT FROM WHMIS LABEL AND SDS REQUIREMENTS.

INGREDIENTS ON INGREDIENT DISCLOSURE LIST: ETHYL ALCOHOL & HYDROGEN PEROXIDE INGREDIENTS WITH UNKNOWN TOXICOLOGICAL PROPERTIES: Product is Exempt.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 2.

#### **SECTION 16: OTHER INFORMATION**

**Labeling:** Hazard: warning: flammable, protect from heat. **Labeling:** This package conforms to 49 CFR 173.4

NC Poison Control Center: 1-800-672-1697

**DISCLAIMER:** The information provided in this Material Data Safety Sheet has been compiled from our experience and data presented in various technical publications. An MSDS for a substance is not primarily intended for use by the general consumer, focusing instead on the hazards of working with the material in an occupational setting. It is believed to be correct, however, it is the user's responsibility to determine the suitability of this information for the adoption of safety precautions deemed necessary. Immunostics, Inc. shall not be held liable for any damage resulting from handling or from contact with the product described in this MSDS. We reserve the right to update MSDS sheets from time to time as new information becomes available. It is the responsibility of the user to verify that they have the latest revision available.

Reviewed

Michael Locke QA/RA Analyst; Senior Lab Date

07/13/2012

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## **NFPA** 704

	Health (Blue)	Flammability (Red)		
0	Poses no health hazard, no precautions necessary (e.g., water)	0	Will not burn (e.g., argon)	
1	Exposure would cause irritation with only minor residual injury (e.g., <u>acetone</u> )	1	Must be heated before ignition can occur (e.g., mineral oil). Flash point over 93°C (200°F)	
2	Intense or continued but not chronic exposure could cause temporary incapacitation or possible residual injury (e.g., ethylether)	2	Must be moderately heated or exposed to relatively high ambient temperature before ignition can occur (e.g., <u>diesel fuel</u> ). Flash point between 38°C (100°F) and 93°C (200°F)	
3	Short exposure could cause serious temporary or moderate residual injury (e.g., <u>chlorine gas</u> )	3	Liquids and solids that can be ignited under almost all ambient temperature conditions (e.g., gasoline). Liquids having a Flash point below 23°C (73°F) and having a Boiling point at or above 38°C (100°F) or having a Flash point between 23°C (73°F) and 38°C (100°F)	
4	Very short exposure could cause death or major residual injury (e.g., <u>hydrogen cyanide</u> , <u>phosphine</u> , <u>carbon monoxide</u> )	4	Will rapidly or completely vaporize at normal atmospheric pressure and temperature, or is readily dispersed in air and will burn readily (e.g., propane, hydrogen). Flash point below 23°C (73°F)	

Instability/Reactivity (Yellow)			Special (White)
0	Normally stable, even under fire exposure conditions, and is not reactive with water (e.g. helium)		The white "special notice" area can contain several symbols. The following symbols are defined by the NFPA 704 standard.
1	Normally stable, but can become unstable at elevated temperatures and pressures (e.g. propene)		
2	Undergoes violent chemical change at elevated temperatures and pressures, reacts violently with water, or may form explosive mixtures with water (e.g., phosphorus, potassium, sodium)	ох	Oxidizer (e.g., potassium perchlorate, ammonium nitrate, hydrogen peroxide)
3	Capable of detonation or explosive decomposition but requires a strong initiating source, must be heated under confinement before initiation, reacts explosively with water, or will detonate if severely shocked (e.g. ammonium nitrate)	₩	Reacts with <u>water</u> in an unusual or dangerous manner (e.g., <u>cesium</u> , <u>sodium</u> , <u>sulfuric acid</u> )
4	Readily capable of <u>detonation</u> or <u>explosive decomposition</u> at normal temperatures and pressures (e.g., <u>nitroglycerine</u> , <u>Trinitrotoluene</u> )		

#### CHEMTREC® (24 hours) 1-800-424-9300

(Toll-free in the U.S., Canada, and the U.S. Virgin Islands)
For calls originating elsewhere:
703-527-3887 (Collect calls are accepted)

## INFOTRAC (24 hours) 1-800-535-5053

(Toll-free in the U.S., Canada, and the U.S. Virgin Islands)
For calls originating elsewhere:
352-323-3500 (Collect calls are accepted)

#### CHEMTEL, INC. (24 hours) 1-888-255-3924

(Toll-free in the U.S., Canada, Puerto Rico and the U.S. Virgin Islands)

For calls originating elsewhere:

## **813-248-0585** (Collect calls are accepted)

#### **3E COMPANY** (24 hours) **1-800-451-8346**

(Toll-free in the U.S., Canada, and the U.S. Virgin Islands)
For calls originating elsewhere:
760-602-8703 (Collect calls are accepted)

The emergency response information services shown above have requested to be listed as providers of emergency response information and have agreed to provide emergency response information to all callers. They maintain periodically updated lists of state and Federal radiation authorities who provide information and technical assistance on handling incidents involving radioactive materials.

## NATIONWIDE POISON CONTROL CENTER (United States Only)

Emergency and information calls are answered by the nearest Poison Center (24 hours): 1-800-222-1222 (toll-free in the U.S.).

#### **NATIONAL RESPONSE CENTER (NRC)**

The NRC, which is operated by the Ù.S. Ćoast Guard, receives reports required when dangerous goods and hazardous substances are spilled. After receiving notification of an incident, the NRC will immediately notify the appropriate Federal On-Scene Coordinator and concerned Federal agencies. Federal law requires that anyone who releases into the environment a reportable quantity of a hazardous substance (including oil when water is, or may be affected) or a material identified as a marine pollutant must **immediately** notify the NRC. When in doubt as to whether the amount released equals the required reporting levels for these materials, the NRC should be notified.

CALL NRC (24 hours) 1-800-424-8802 (Toll-free in the U.S., Canada, and the U.S. Virgin Islands) 202-267-2675 in the District of Columbia

Calling the emergency response telephone number, CHEMTREC®, CHEMTEL, INC., INFOTRAC or 3E COMPANY, does not constitute compliance with regulatory requirements to call the NRC.



Fecal Occult Blood Test, *FOBT*, Slides (Hema Screen™)

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#### **SECTION 1: PRODUCT IDENTIFICATION**

PRODUCT NAME: Hema Screen™ Fecal Occult Blood Test (FOBT) (GUAIAC SLIDES)

SYNONYMS: FOBT/gFOBT

**PRODUCT DESCRIPTION:**  Manufactured by impregnation of Guaiac gum, Gum guaiac, Gum guaiacum, Guaiacum. Fecal occult blood (FOB) refers to blood in the feces that is not visibly apparent. A fecal occult blood test (FOBT) checks for hidden (occult) blood in the stool (feces), more specifically stool guaiac tests look for heme.

Stool guaiac test for fecal occult blood (gFOBT): - The stool guaiac test involves smearing some feces on to some absorbent paper that has been treated with a chemical. Hydrogen peroxide is then dropped on to the paper; if trace amounts of blood are present, the paper will change color in one or two seconds. This method works as the heme component in hemoglobin has a peroxidase-like effect, rapidly breaking down hydrogen peroxide. In some settings such as gastric or proximal upper intestinal bleeding the guaiac method may be more sensitive than tests detecting globin because globin is broken down in the upper intestine to a greater extent than is heme. Optimal clinical performance of the stool guaiac test depends on preparatory dietary adjustment.

Guaiac gum: The resin from the wood of Guaiacum officinale L., or of Guaiacum sanctum L., (Fam. Zygophyllaceae), consisting of approximately 70% alpha- and beta-guaiaconic acids, 10% guaiaretic acid, and 15% guaiac beta-resin and small quantities of guaiac yellow, vanillin,

> Irregular lumps enclosing fragments of vegetable tissues; or large, nearly homogeneous masses and occasionally more or less rounded or ovoid tears; externally, it is brownish black to dusky brown, acquiring a greenish colour on long exposure, the fractured surface having a glassy lustre, the thin pieces being transparent and varying in color from brown to yellowish orange; the powder is moderate yellow brown, becoming olive brown on exposure to air. It has a mild balsamic odor.

PREPARATION: The trunk of guaiacum by the more invasive tree trunk in the West Indies was

crushed, and put it in heated ethanol and filtrated it. After the fractional

distillation of ethanol from the solution, gum guaiac was produced.

**USES OF GUM GUAIAC:** Gum guaiac is mainly used for anti-oxidants and preservatives of the chewy gum bodying agent, buttermilk and fat. When used as antioxidants for

vegetable oil and butter, the amount of gum guaiac shall not exceed 1g/kg.

PREPARATION: hema-screen<sup>TM</sup> slides feature special electrophoresis filter paper impregnated with guaiac. Since the guaiac

is not in solution, it will remain stable for three years.

**USES:** Fecal occult blood testing (FOBT), as its name implies, aims to detect subtle blood loss in the gastrointestinal

Positive tests ("positive stool") may result from gastrointestinal bleeding and warrant further investigation for peptic ulcers or a malignancy (such as colorectal cancer or gastric cancer). The test does not directly detect colon cancer but is often used in clinical screening for that disease, but it can also be used

to look for active occult blood loss in anemia or when there are gastrointestinal symptoms.

hema-screen™ is a rapid, convenient, and non-offensive qualitative method for detecting occult blood in the stool. It is intended for professional use as an aid in the diagnosis of asymptomatic gastrointestinal conditions that may manifest themselves by the presence of occult blood in the stool. This test is recommended for use in routine hospital testing, mass screening programs for colorectal cancer, and in

testing of postoperative patients and newborn infants.

#### **SECTION 3: HAZARDS IDENTIFICATION**

**EMERGENCY OVERVIEW:** Non-Hazardous

**ROUTES OF ENTRY:** 

POTENTIAL HEALTH EFFECTS

EYES: Non-Irritating

SKIN: None INGESTION: None INHALATION: N/A **ACUTE HEALTH HAZARDS:** N/A

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**CHRONIC HEALTH HAZARDS:** N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: None

SECTION 4: FIRST AID MEASURES

EYES: N/A

SKIN: Wash off with soap and water. No irritation is expected.

INGESTION: Physician may induce vomiting. INHALATION: No adverse affect is expected.

**SECTION 5: FIRE-FIGHTING MEASURES** 

FLAMMABLE LIMITS IN AIR, UPPER: N/A FLASH POINT: N/A **AUTOIGNITION TEMPERATURE:** N/A

NFPA HAZARD CLASSIFICATION

**HEALTH:** 1 **FLAMMABILITY:** 0 **REACTIVITY**:

HMIS HAZARD CLASSIFICATION

HEALTH: N/A PROTECTION: FLAMMABILITY: N/A REACTIVITY: N/A

**EXTINGUISHING MEDIA:** N/A **SPECIAL FIRE FIGHTING PROCEDURES:** N/A **UNUSUAL FIRE AND EXPLOSION HAZARDS:** N/A **HAZARDOUS DECOMPOSITION PRODUCTS:** N/A

**SECTION 6: ACCIDENTAL RELEASE MEASURES** 

ACCIDENTAL RELEASE MEASURES:

**SECTION 7: HANDLING AND STORAGE** 

HANDLING AND STORAGE: Store at room temperature (15°-30°C or 59°-86°F). Do not refrigerate or freeze. Protect from heat,

humidity, and light. Do not store with volatile chemicals, e.g. iodine, chlorine (bleach), bromine or ammonia. When stored as recommended, slides will maintain sensitivity up to three years from date of manufacture. The guaiac slides are beige in color. However, if not stored as recommended, they

may discolor and turn blue. Do not use after expiration date.

**OTHER PRECAUTIONS:** 

For in vitro diagnostic use. Do not substitute reagents from kits from other manufacturers. You may interchange slides & reagent from Immunostics hema-screen  $^{\text{TM}}$  kits as long as they are within the expiration date. Patient specimens and all materials coming into contact with them should be

handled as if capable of transmitting infections and disposed of with proper precautions.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**VENTILATION: NONE** 

**RESPIRATORY PROTECTION: NONE** 

**EYE PROTECTION: NONE** 

SKIN PROTECTION: Polyethylene Gloves

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

**EXPOSURE LIMITS: N/A** 

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES** 

APPEARANCE: Light brown/Beige in color ODOR: mild balsamic/vanillin Organic odor

pH AS SUPPLIED: N/A

VAPOR PRESSURE (mmHg): N/A VAPOR DENSITY (AIR = 1): N/A



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Fecal Occult Blood Test, *FOBT*, Slides (Hema Screen™)

MSDS DATE: 07/13/2012

SPECIFIC GRAVITY (H2O = 1): N/A

**SOLUBILITY IN WATER: RENDERS TEST INVALID** 

GUAIAC: Insoluble in water; soluble in fats; dissolves readily but incompletely in ethanol, ether, and solutions of alkalis.

**PERCENT SOLIDS BY WEIGHT: 100%** 

**PERCENT VOLATILE: NONE** 

**SECTION 10: STABILITY AND REACTIVITY** 

**STABILITY: 3 YEARS** 

CONDITIONS TO AVOID (STABILITY): Store at room temperature (15°-30°C or 59°-86°F). Do not refrigerate or freeze. Protect

from heat, humidity, and light.

INCOMPATIBILITY (MATERIAL TO AVOID): Do not store with volatile chemicals, e.g. iodine, chlorine (bleach), bromine or ammonia.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: NONE HAZARDOUS POLYMERIZATION: NONE EXPECTED

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Eyes: No irritant Skin: No irritation expected

 Respiratory:
 None
 Oral LD50:
 N/A

 Dermal LD50:
 N/A
 Chronic Toxicity:
 None

 Carcinogenicity:
 None
 Mutanogenicity:
 None

Teratogenicity: None Occupational Exposure: No adverse effect expected

Limits: None Other: None

**SECTION 12: ECOLOGICAL INFORMATION** 

**ECOLOGICAL INFORMATION:** Not Applicable

**SECTION 13: DISPOSAL CONSIDERATIONS** 

WASTE DISPOSAL METHOD: No procedure necessary.

WITH SPECIMEN: Patient specimens and all materials coming into contact with them should be handled as if capable of

transmitting infections and disposed of with proper precautions.

**SECTION 14: TRANSPORT INFORMATION** 

U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: Laboratory chemicals - non hazardous, Class 85

HAZARD CLASS: ID NUMBER: PACKING GROUP: LABEL STATEMENT:

WATER TRANSPORTATION

PROPER SHIPPING NAME: Laboratory chemicals – non hazardous, Class 85

HAZARD CLASS: ID NUMBER: PACKING GROUP: LABEL STATEMENTS:

AIR TRANSPORTATION

PROPER SHIPPING NAME: Laboratory chemicals - non hazardous, Class 85

HAZARD CLASS: ID NUMBER: PACKING GROUP: LABEL STATEMENTS:

**SECTION 15: REGULATORY INFORMATION** 

**U.S. FEDERAL REGULATIONS** 

TSCA (TOXIC SUBSTANCE CONTROL ACT): None



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Fecal Occult Blood Test, *FOBT*, Slides (Hema Screen™)

MSDS DATE: 07/13/2012

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): None SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT): None

QA/RA Analyst; Senior Lab

311/312 HAZARD CATEGORIES: None

313 REPORTABLE INGREDIENTS: Not Reportable

**SECTION 16: OTHER INFORMATION** 

DISCLAIMER: The information provided in this Material Data Safety Sheet has been compiled from our experience and data presented in various technical publications. It is believed to be correct, however, it is the user's responsibility to determine the suitability of this information for the adoption of safety precautions deemed necessary. Immunostics, Inc. shall not be held liable for any damage resulting from handling or from contact with the product described in this MSDS. We reserve the right to update MSDS sheets from time to time as new information becomes available. It is the responsibility of the user to verify that they have the latest revision available.

**Reviewed** 

**Date** 07/13/2012



