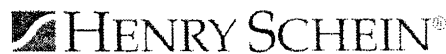


MATERIAL SAFETY DATA SHEET
Fecal Occult Blood Test, Slides (One Step™)



MSDS DATE: 11/08/2012

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: One Step™ Fecal Occult Blood Test (FOBT) (GUAIAIC SLIDES)

SYNONYMS: FOBT/gFOBT

PRODUCT DESCRIPTION: Manufactured by impregnation of *Guaiaec gum, Gum guaiac, Gum guaiacum, Guaiaecum*. 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.

Guaiaec gum: The resin from the wood of *Guaiaecum officinale* L., or of *Guaiaecum sanctum* L., (Fam. Zygophyllaceae), consisting of approximately 70% alpha- and beta-guaiaeconic acids, 10% guaiaecetic acid, and 15% guaiac beta-resin and small quantities of guaiac yellow, vanillin, etc.

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 gualacum 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 GUAIAEC: 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: One Step™ 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 tract. 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.

One Step™ 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.

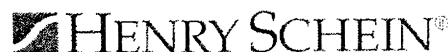
SECTION 3: HAZARDS IDENTIFICATION

COMPOSITION:

IUPAC	SYNONYMS	MOLECULAR FORMULA	IDENTIFIERS										
Guaiaec	guaiaec resin, guaiacum spp., guaiacum (resin), gum guaiac, gum guaiacum	N/A	<table border="1"> <tr> <td>CAS</td> <td>9000-29-7</td> </tr> <tr> <td>PUBCHEM</td> <td>N/A</td> </tr> <tr> <td>EC</td> <td>232-535-2</td> </tr> <tr> <td>UN</td> <td>N/A</td> </tr> <tr> <td>RTEC</td> <td>ME6260000</td> </tr> </table>	CAS	9000-29-7	PUBCHEM	N/A	EC	232-535-2	UN	N/A	RTEC	ME6260000
CAS	9000-29-7												
PUBCHEM	N/A												
EC	232-535-2												
UN	N/A												
RTEC	ME6260000												

EMERGENCY OVERVIEW: Non-Hazardous

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ROUTES OF ENTRY:

POTENTIAL HEALTH EFFECTS

EYES: Non-Irritating
SKIN: None
INGESTION: None
INHALATION: N/A

ACUTE HEALTH HAZARDS: N/A

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:** 0

HMIS HAZARD CLASSIFICATION

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

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 Henry Schein® One Step™ FOB 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

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 **HENRY SCHEIN®**
MSDS DATE: 11/08/2012

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

SPECIFIC GRAVITY (H₂O = 1): N/A

SOLUBILITY IN WATER: RENDERS TEST INVALID

GUAJAC: 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

MATERIAL SAFETY DATA SHEET
Fecal Occult Blood Test, Slides (One Step™)



MSDS DATE: 11/08/2012

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

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

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. 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. Henry Schein® 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.

NFPA 704

Health (Blue)		Flammability (Red)	
0	Poses no health hazard, no precautions necessary (e.g., <u>water</u>)	0	Will not burn (e.g., <u>argon</u>)
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., <u>mineral oil</u>). 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., <u>ethyl ether</u>)	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., <u>gasoline</u>). 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., <u>propane</u> , <u>hydrogen</u>). 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., <u>helium</u>)	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., <u>propene</u>)		
2	Undergoes violent chemical change at elevated temperatures and pressures, reacts violently with water, or may form explosive mixtures with water (e.g., <u>phosphorus</u> , <u>potassium</u> , <u>sodium</u>)	OX	<u>Oxidizer</u> (e.g., <u>potassium perchlorate</u> , <u>ammonium nitrate</u> , <u>hydrogen peroxide</u>)
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., <u>ammonium nitrate</u>)	W	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 detonation or explosive decomposition 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)	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)
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)	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 U.S. Coast 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.