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MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
175	OSOM[®] H. pylori

Item Number:	Component Name:
P-2261	OSOM[®] H. pylori Developer Solution

Note: There are a total of 7 pages including this cover sheet.

OSOM[®] H. pylori cassette is an "article" and does not require an MSDS.



MATERIAL SAFETY DATA SHEET

OSOM® H. pylori Developer Solution

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: OSOM® H. pylori Developer Solution

Product Number: P-2261

Kit Number: 175

Product Use: Component of OSOM H. pylori kit. For the in vitro qualitative detection of anti-Helicobacter pylori IgG antibody in human whole blood, serum, or plasma specimens. For In Vitro Diagnostic Use Only.

Description: Dilute aqueous solution containing preservative.

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Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555

CHEMTREC (U.S.): 800-424-9300

CHEMTREC (Outside U.S.): +1 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	No data available.
Eye	No data available. Eye exposure may cause irritation, redness and watering.
Skin	No data available. Skin contact may cause irritation, dryness and redness.
Ingestion	No data available. Ingestion may produce nausea, vomiting, and diarrhea.
Chronic Effects	No data available.
Target Organs	Unknown.

Regulatory Status:

This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.



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Potential Environmental Effects:

See Section 12.

3. COMPOSITION / INFORMATION ON INGREDIENTS

No hazardous ingredients are present at or above the minimum concentration limits requiring disclosure per U.S. and international MSDS regulations.

4. FIRST AID MEASURES

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

Do not dispose down the drain.

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.



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7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2 to 30°C (35 to 86°F). Do not store with incompatible substances; see Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

Engineering Controls:

This preparation is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory	A respirator is not required under normal conditions of use.
Eye/Face	Wear appropriate protective chemical safety glasses.
Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	pH:	7.0 - 7.4
Odor:	Odorless	Solubility:	Water-soluble
Boiling Point:	Not available	Evaporation Rate:	Not available
Melting Point:	Not applicable	Density:	Not available
Freezing Point:	Not available	Vapor Pressure:	Not available
Viscosity:	Not available	Partition Coefficient (n-octanol/water):	Not available
		Vapor Density:	Not available
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	Not available		



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10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

Incompatible Materials:

Unknown.

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

No data available.

Local Effects:

No data available.

Chronic Effects:

No data available.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.



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13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

Do not pour this preparation down the drain. Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canadian Hazardous Products:

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class None

Risk Phrases None

Safety Phrases None

16. OTHER INFORMATION

Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

MSDS Origination Date: June 25, 2009

Version #: 1

Revision Date: Not Applicable



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