

1. Identification

Product identifier	OSOM® H. pylori Developer Solution
Other means of identification	
Kit number	175
Recommended 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.
Recommended restrictions	Use in accordance with supplier's recommendations.
Manufacturer/Importer/Supplier/Distributor information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, USA www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962
Emergency Telephone Numbers	Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 Access code 333512

2. Hazard(s) identification

Physical hazards	Not classified.
Health Hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	None.
Response	None.
Storage	None.
Disposal	None.
Hazard(s) not otherwise classified (HNOC)	None known.

3. Composition/information on ingredients

Mixtures

The components are not hazardous or are below required disclosure limits.

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Ingestion	If material is ingested, immediately contact a poison control center.
Most important symptoms/effects, acute and delayed	Ingestion of sodium azide may cause nausea, diarrhea, vomiting, headache, slight lowering of blood pressure, abdominal pain, and a general feeling of apprehension and unwellness.

Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
5. Fire-fighting measures	
Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	None known.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	The product is not flammable.
6. Accidental release measures	
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Methods and materials for containment and cleaning up	Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
Environmental precautions	Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.
7. Handling and storage	
Precautions for safe handling	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
Conditions for safe storage, including any incompatibilities	Store at 2 to 30°C (35 to 86°F). Store in a closed container away from incompatible materials.
8. Exposure controls/personal protection	
Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Follow standard monitoring procedures.
Appropriate engineering controls	Use general ventilation.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear approved safety glasses or goggles.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	Under normal conditions, respirator is not normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
9. Physical and chemical properties	
Appearance	Clear, colorless liquid.
Physical state	Liquid.
Form	Liquid.
Color	Clear, colorless.
Odor	Odorless.
Odor threshold	Not available.

pH	7 - 7.4
Melting point/freezing point	Not applicable.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non reactive under normal conditions of storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Protect against direct sunlight.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Vapors may irritate throat and respiratory system and cause coughing.
Skin contact	Prolonged skin contact may cause redness, irritation and dry skin. Sodium azide may be absorbed through the skin and result in systemic effects.
Eye contact	Splashes in the eyes may cause redness and irritation.
Ingestion	May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics May cause eye irritation on direct contact.

Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
Skin corrosion/irritation	Sodium azide may be absorbed through the skin and result in systemic effects.
Serious eye damage/eye irritation	Splashes in the eyes may cause redness and irritation.
Respiratory or skin sensitization	
Respiratory sensitization	Not classified.
Skin sensitization	No data available.

Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Chronic effects	No data available.
Further information	No other specific acute or chronic health impact noted.

12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	Not available.
Mobility in general	The product is soluble in water.
Other adverse effects	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up.
Hazardous waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose in accordance with all applicable regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code This substance/mixture is not intended to be transported in bulk.

15. Regulatory information

US federal regulations This product is not hazardous according to OSHA 29CFR 1910.1200. All components are on the U.S. EPA TSCA Inventory List. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

International Inventories

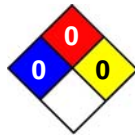
Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 13-October-2014
Revision date -
Version # 01

NFPA ratings**References**

ACGIH
HSDB® - Hazardous Substances Data Bank
IARC Monographs. Overall Evaluation of Carcinogenicity

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