

* MATERIAL SAFETY DATA SHEET *

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: CONSULT® H. Pylori Cassette Test
MFR #: 5007 (10/BX); 5008 (25/BX)

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
8741 Landmark Road
Richmond, VA 23228

INFORMATION LINE: 1-800-777-4908

EMERGENCY PHONE: 1-800-424-9300 (CHEMTREC)

PRODUCT DESCRIPTION: In vitro diagnostic medical device. Test strip impregnated with dried chemical / biochemical reagents.

SECTION 2: COMPOSITION/INFORMATION OF INGREDIENTS

<u>INGREDIENT</u>	<u>CAS NO.</u>		<u>%</u>	<u>Exposure Limits</u>
Tris (hydroxymethyl) aminomethane	77-86-1	201-064-4	Xi, R 36/377/38	2—5%
Na4EDTA	64-02-8	200-573-9	Xn, R22-41	2—5%

SECTION 2 NOTES: Each device is packaged in a foil pouch. As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.

SECTION 3: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Skin contact, Eye contact

POTENTIAL HEALTH EFFECTS:

EYES: Irritating effect following contact with the chemicals impregnated in the test strip

SKIN: No irritating effects anticipated.

INGESTION: N/A

INHALATION: N/A

ACUTE HEALTH HAZARDS: N/A

CHRONIC HEALTH HAZARDS: N/A

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N/A

CARCINOGENICITY

OSHA: N/A

ACGIH: N/A

NTP: N/A

IARC: N/A

OTHER: N/A

SECTION 3 NOTES: N/A

SECTION 4: FIRST-AID MEASURES

The following first-aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the test strip.

EYES: Immediately rinse opened eye for several minutes under running water.

SKIN: Wash with soap and water and rinse thoroughly.

INGESTION: If desiccant or other components are swallowed seek medical attention.

INHALATION: N/A

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS: N/A

SECTION 4 NOTES: N/A

SECTION 5: FIRE-FIGHTING MEASURES

FLAMMABLE LIMITS IN AIR, UPPER: N/A
(% BY VOLUME) LOWER: N/A

FLASH POINT: N/A
METHOD USED: N/A

AUTOIGNITION TEMPERATURE: N/A

NFPA HAZARD CLASSIFICATION

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

HMS HAZARD CLASSIFICATION

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

EXTINGUISHING MEDIA: CO₂, power or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire-extinguishing methods suitable to surrounding conditions.

SPECIAL FIRE FIGHTING PROCEDURES: Wear full protective suit and self-contained respiratory protective device when extinguishing fires.

UNUSUAL FIRE AND EXPLOSION HAZARDS: The device contains combustible materials. Product does not present an explosion hazard.

HAZARDOUS DECOMPOSITION PRODUCTS: In case of fire the following may be released: Hazardous fumes and vapors, carbon oxides and nitrogen oxides.

SECTION 5 NOTES: N/A

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Collect material and dispose of as waste according to Section 13. Avoid releasing into the environment.

SECTION 6 NOTES: Refer to Section 8 for protective measures when handling the spillage.

SECTION 7: HANDLING AND STORAGE

HANDLING: N/A

STORAGE: Store in the original container at 2–30°C

OTHER PRECAUTIONS: Keep out of reach of children

SECTION 7 NOTES: N/A

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

VENTILATION: Use in a well-ventilated area

RESPIRATORY PROTECTION: Not required

EYE PROTECTION: Not required

SKIN PROTECTION: Latex/natural disposable gloves (for sampling handling). Lab coat. NOTE—Glove resistance is not critical as the gloves are intended to provide protection against the sample material.

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

WORK HYGIENIC PRACTICES: Specimens should be handled as potentially infectious materials. Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

EXPOSURE GUIDELINES: The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

SECTION 8 NOTES: N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE & ODOR: Laminated test strip, housed in a plastic holder. Odorless.

PHYSICAL STATE: The device is an article containing solid components.

pH AS SUPPLIED: N/A

pH (Other): N/A

BOILING POINT: N/A

MELTING POINT: N/A

FREEZING POINT: N/A

VAPOR PRESSURE (mmHg): N/A

@ N/A

DENSITY (lb/gal): N/A

@ N/A

SPECIFIC GRAVITY (H₂O = 1): N/A

@ N/A

EVAPORATION RATE: N/A

BASIS (=1): N/A

SOLUBILITY IN WATER:

PERCENT SOLIDS BY WEIGHT: N/A

PERCENT VOLATILE: N/A

BY WT/ N/A BY VOL @ N/A

VOLATILE ORGANIC COMPOUNDS (VOC): N/A

WITH WATER: N/A LBS/GAL

WITHOUT WATER: N/A LBS/GAL

MOLECULAR WEIGHT: N/A

VISCOSITY: N/A

SECTION 9 NOTES: N/A

SECTION 10: STABILITY AND REACTIVITY

STABLE

UNSTABLE

STABILITY: X

CONDITIONS TO AVOID (STABILITY): The product is stable in accordance with the recommended storage conditions.

INCOMPATIBILITY (MATERIAL TO AVOID): None

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: No dangerous decomposition products known.

HAZARDOUS POLYMERIZATION: N/A

CONDITIONS TO AVOID (POLYMERIZATION): N/A

SECTION 10 NOTES: N/A

SECTION 11: TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION: Quantitative data on the toxic effects of this product is not available; No sensitizing effects known

SECTION 11 NOTES: N/A

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: Quantitative data on the toxic effects of this product is not available. The device contains plastic and other components that are not readily degradable.

SECTION 12 NOTES: N/A

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Used devices and other contaminated materials should be disposed of as potentially bio hazardous waste. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. Disposal must be made in accordance with local waste management regulations. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

RCRA HAZARD CLASS: N/A

SECTION 13 NOTES: N/A

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION

PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
DOT SHIPPING ID NUMBER: N/A
DOT PACKING GROUP: N/A
DOT HAZARD CLASS: N/A
DOT LABEL STATEMENT: N/A

WATER TRANSPORTATION

PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
ID NUMBER: N/A
PACKING GROUP: N/A
LABEL STATEMENTS: N/A

AIR TRANSPORTATION

PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
ID NUMBER: N/A
PACKING GROUP: N/A
LABEL STATEMENTS: N/A

SECTION 14 NOTES: Not regulated for transport.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TSCA (TOXIC SUBSTANCE CONTROL ACT): N/A

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): N/A



MSDS DATE: 01/13/2015

SARA 311/312 HAZARD CATEGORIES: N/A

SARA 313 REPORTABLE INGREDIENTS: Contains NO hazardous ingredients subject to reporting requirements of Section 313 of SARA Title II.

STATE REGULATIONS: N/A

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: N/A

PREPARATION INFORMATION: N/A

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.