

MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: CONSULT® Strep A Test
REORDER #: 4999 (50T/Kit); 5003 (25T/Kit)

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. For professional use only.

SECTION 2: COMPOSITION/INFORMATION OF INGREDIENTS

<u>INGREDIENT</u>	<u>CAS NO.</u>	<u>EINECS NO.</u>	<u>CLASSIFICATION</u>	<u>CONCENTRATION %</u>
Tris (hydroxymethyl) aminomethane	77-86-2	201-064-4	Xi, R 36/37/38	10—20%
Sodium Carbonate	497-19-8	207-838-8	Xi, R 36	5—10%

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

SECTION 3: HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Eye contact, skin contact

POTENTIAL HEALTH EFFECTS

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

strip. **SKIN:** Contact with the chemicals impregnated in the test strip may cause

mild irritation **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. Seek medical advice.

SKIN: Wash with soap and water and rinse thoroughly. Consult a doctor if irritation persists.

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: Not self-igniting

NFPA HAZARD CLASSIFICATION

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

HMIS HAZARD CLASSIFICATION

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

EXTINGUISHING MEDIA: CO2, powder 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:

SECTION 6: ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Collect material and dispose of as waster according to Section 13. Avoid release to 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: N/A

RESPIRATORY PROTECTION: Not required

EYE PROTECTION: Not required

SKIN PROTECTION: Latex/natural rubber disposable gloves (for sample handling); Lab coat

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; 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

VAPOR DENSITY (AIR = 1): N/A

@ N/A

SPECIFIC GRAVITY (H₂O = 1): N/A

@ N/A

EVAPORATION RATE:

N/A **BASIS (=1):** N/A

SOLUBILITY IN WATER:

N/A

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

@
N/
A

SECTION 9 NOTES: N/A

SECTION 10: STABILITY AND REACTIVITY

STABLE

UNSTABLE

STABILITY: X

CONDITIONS TO AVOID (STABILITY): None

INCOMPATIBILITY (MATERIAL TO AVOID): None

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: No dangerous decomposition product 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 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 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
311/312 HAZARD CATEGORIES: N/A
313 REPORTABLE INGREDIENTS:

N/A STATE REGULATIONS: N/A

INTERNATIONAL REGULATIONS: N/A

SECTION 15 NOTES: N/A

SECTION 16: OTHER INFORMATION

OTHER INFORMATION: Labeling according to EU guidelines: Code letter and hazard designation of product: Xi (Irritant)

RISK PHRASES: 36 Irritating to Eyes

SAFETY PHRASES: S2 Keep out of reach of children; 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice; 46 If swallowed, seek medical advice immediately and show this container or label; 60 This material and its container must be disposed of as hazardous waste.

PREPARATION INFORMATION: The preparation is exempt from the above labeling requirements in accordance to Article 12.2 of Directive 99/45/EC as the form in which it is placed on the market does not present any significant risk to man or the environment when used according to the instructions for use.

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.