SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT NAME: CONSULT® hCG Dipstick (5000), CONSULT® hCG Urine Cassette Test (5001), CONSULT® hCG Combo cassette test (5002).

MFR #: 5000 (Dipstick); 5001 (Cassette); 5002 (Combo Cassette)

DISTRIBUTED BY: McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908 Monday-Friday 8:00 a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-451-8346 (3E Company) Day or Night

PRODUCT DESCRIPTION/IDENTIFIED USES: In vitro diagnostic reagent. For professional use only.

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP)
Hazard statement(s) Eye Irrit. 2
H319: Causes serious eye irritation.


Eye Irrit. 2
Hazard statement(s) Causes serious eye irritation.

2.2 Label elements

No measures required. The product is placed on the market in the form of an article, which contains insignificant quantities of hazardous chemicals that are not intended to be released from the device.

2.3 Other hazards

None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Description: In vitro diagnostic reagent test device. Preparation. Laminated test strip consisting of solid support materials impregnated with dried chemical / biochemical reagents.

Dangerous components:
EC Classification No. 1272/2008 / GHS

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>%W/W</th>
<th>EC No.</th>
<th>CAS No.</th>
<th>Classification code:</th>
<th>Hazard statement(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium carbonate</td>
<td>1 - 2</td>
<td>207-838-8</td>
<td>497-19-8</td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
<tr>
<td>Triton X100*</td>
<td>1 - 2</td>
<td>-</td>
<td>9002-93-1</td>
<td>Acute Tox. 4; H302</td>
<td>Eye Dam. 1; H318; Aquatic Chronic 2; H411</td>
</tr>
<tr>
<td>Sodium azide**</td>
<td>&lt; 0.1</td>
<td>247-852-1</td>
<td>26628-22-8</td>
<td>Acute Tox. 2; H300</td>
<td>Aquatic Acute 1; H400; Aquatic Chronic 1; H410; EUH032</td>
</tr>
</tbody>
</table>

EC Classification No.67/548/EEC

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>%W/W</th>
<th>EC No.</th>
<th>CAS No.</th>
<th>EC Classification and Risk Phrases</th>
</tr>
</thead>
</table>

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SAFETY DATA SHEET


| Sodium carbonate | 1 - 2 | 207-838-8 | 497-19-8 | Xi; R36 |
| Triton X100* | 1 - 2 | - | 9002-93-1 | Xn; R22-41-51/53 |
| Sodium azide** | < 0.1 | 247-852-1 | 26628-22-8 | T+, N; R28-32-50/53 |

* candidate substance of very high concern (SVHC)
** Substance with a community exposure limit

3.3 Additional Information
For full text of R/H phrases see section 16. Each device is packaged in a foil pouch.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures
General information
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.

Inhalation
Supply fresh air; consult doctor in case of complaint.

Skin Contact
Wash skin with soap and water.

Eye Contact
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed
None.

4.3 Indication of the immediate medical attention and special treatment needed
None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media
Suitable Extinguishing Media
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture
In case of fire, the following can be released: Hazardous fumes, Carbon oxides (COx), nitrogen oxides (NOx).

5.3 Advice for fire-fighters
Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions
Avoid release to the environment.

6.3 Methods and material for containment and cleaning up
Collect material and dispose of as waste according to Section 13.

6.4 Reference to other sections
8, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling
Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials. Avoid contact with the eyes, skin and mucous membranes. Keep out of reach of children. Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent.

7.2 Conditions for safe storage, including any incompatibilities

Store in the original container at 2 to 30°C.

7.3 Specific end use(s)

Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits

EU IOELV / UK WEL / IrOELV

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>CAS No.</th>
<th>LTEL (8 hr TWA ppm)</th>
<th>LTEL (8 hr TWA mg/m³)</th>
<th>STEL (ppm)</th>
<th>STEL (mg/m³)</th>
<th>Note:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>0.1</td>
<td>0.3</td>
<td>Sk</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sk - Can be absorbed through skin.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Not relevant for this material.

8.2.2 Personal protection equipment

Eye/face protection
Safety glasses recommended. (EN166)

Hand protection
Disposable gloves. (EN374).

Material of gloves: Latex / natural rubber, Nitrile rubber.
Penetration time of glove material: Gloves resistance is not critical when the product is handled according to the instructions for use.
Body protection
Laboratory coat.
Respiratory protection
Not normally required.

8.2.3 Environmental Exposure Controls

No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance
Laminated test strip, which may be housed in a plastic holder.

Colour
Variable depending on product.

Odour
No odour.

Odour Threshold (ppm)
Not applicable.

pH (Value)
Not determined.

Melting Point (°C) / Freezing Point (°C)
Not determined.

Boiling point/boiling range (°C):
Not determined.

Flash Point (°C)
Not applicable.

Evaporation rate (BA = 1)
Not applicable.

Flammability (solid, gas)
Not determined.

Explosive limit ranges
Not applicable.

Vapour Pressure (mm Hg)
Not applicable.

Vapour Density (Air=1)
Not applicable.

Density (g/ml)
Not applicable.

Solubility (Water)
Not determined.

Solubility (Other)
Not determined.

Partition Coefficient (n-Octanol/water)
Not determined.

Auto Ignition Temperature (°C)
Not determined.

Decomposition Temperature (°C)
Not determined.

Viscosity (mPa.s)
Not applicable.

Explosive properties
Not explosive.

Oxidising properties
Not oxidising

9.2 Other information

Not available.
SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity
None known.

10.2 Chemical stability
The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions
Contact with acids may liberate trace amounts of toxic gas (hydrazoic acid). Hazardous polymerisation will not occur.

10.4 Conditions to avoid
None.

10.5 Incompatible materials
None.

10.6 Hazardous Decomposition Product(s)
None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures
Acute toxicity
Based upon the available data, the classification criteria are not met.

Irritation
Causes serious eye irritation.

Corrosivity
Based upon the available data, the classification criteria are not met.

Sensitisation
Based upon the available data, the classification criteria are not met.

Repeated dose toxicity
Based upon the available data, the classification criteria are not met.

Carcinogenicity
Based upon the available data, the classification criteria are not met.

Mutagenicity
Based upon the available data, the classification criteria are not met.

Toxicity for reproduction
Based upon the available data, the classification criteria are not met.

STOT-single exposure
Based upon the available data, the classification criteria are not met.

STOT-repeated exposure
Based upon the available data, the classification criteria are not met.

Aspiration hazard
Based upon the available data, the classification criteria are not met.

11.2 Other information
Not applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity
The product does not contain significant quantities of ingredients that are environmentally toxic.

12.2 Persistence and degradability
The device contains plastic and other components that are not readily degradable.

12.3 Bioaccumulative potential
None anticipated.

12.4 Mobility in soil
The product is predicted to have low mobility in soil.

12.5 Results of PBT and vPvB assessment
Not applicable.

12.6 Other adverse effects
Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Product:
Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. Disposal should be in accordance with local, state or national legislation. To ensure compliance we recommend that you contact the relevant (local) authorities and/oran
approved waste-disposal company for information.

European waste catalogue: 18 01 03.

Packaging: Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number Not applicable
14.2 UN Proper Shipping Name Not applicable
14.3 Transport hazard class(es) Not classified as dangerous for transport.
14.4 Packing Group Not applicable
14.5 Environmental hazards Not applicable
14.6 Special precautions for user Not applicable
14.7 MARPOL73/78 and the IBC Code Not applicable

SECTION 15: REGULATORY INFORMATION


Carcinogen listings
IARC: None of the ingredients is listed.
NTP: None of the ingredients is listed.
ACGIH: None of the ingredients is listed.
OSHA: None of the ingredients is listed.
EPA: None of the ingredients is listed.

Californian Proposition 65
Chemicals known to cause cancer: None of the ingredients is listed.
Chemicals known to cause reproductive toxicity: None of the ingredients is listed.

SARA
Section 355 (extremely hazardous substances): Sodium azide (trace).
Section 313 (specific toxic chemical listings): Sodium azide (trace).

15.2 Chemical Safety Assessment Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND
STOT Specific Target Organ Toxicity
STEL Short Term Exposure Limit
LTE L Long Term Exposure Limit
TWA Time Weighted Average

Classification code:
Acute Tox. 4 Acute toxicity; Category 4
Acute Tox. 2 Acute toxicity; Category 2
Eye Dam. 1 Eye damage; Category 1
Eye Irrit. 2 Eye irritation; Category 2
Aquatic Acute 1 Hazardous to the aquatic environment Acute: Category 1
Aquatic Chronic 1 Hazardous to the aquatic environment Chronic: Category 1
Aquatic Chronic 2 Hazardous to the aquatic environment Chronic: Category 2
Hazard statement(s)
H300: Fatal if swallowed.
H302: Harmful if swallowed.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H411: Toxic to aquatic life with long lasting effects.
EUH032: Contact with acids liberates very toxic gas.

Risk Phrases
R22: Harmful if swallowed.
R28: Very toxic if swallowed.
R32: Contact with acids liberates very toxic gas.
R36: Irritating to eyes.
R41: Risk of serious damage to eyes.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

References:
Raw material safety data sheets.

DISCLAIMER: This information relates onto 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.