IDENTIFICATION

Product Name: HALYARD* PYTEST* Capsules
Product Number: 60438

Date Prepared: 5/13/16
Manufacturer: Halyard Health Inc.
5405 Windward Parkway
Alpharetta, Georgia 30004

Telephone:
MEDICAL EMERGENCY:
TRANSPORTATION EMERGENCY:
INFORMATION:
Call 911 or your local Emergency Room or Poison Control Services
Chemtrec 1-800-424-9300 or 1-703-527-3887 (collect calls accepted)
1-844-HALYARD

Product Use: Medical diagnostic test

2. HAZARDS IDENTIFICATION

GHS Classification: Not Hazardous
GHS Labeling: No GHS labeling required.

3. COMPOSITION INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No./ EINECS-No</th>
<th>%</th>
<th>GHS Classification:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-hazardous ingredients</td>
<td>Proprietary</td>
<td>99-100</td>
<td>Not Hazardous</td>
</tr>
<tr>
<td>C14 Radioactive Urea</td>
<td>57-13-6 / 200-315-5</td>
<td>0.4</td>
<td>Not Hazardous</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

The test produces radiation exposure equal to 24 hours of normal background. In animal experiments, such low doses of radiation do not carry measurable risk.

Inhalation: No first aid should be needed.

Skin contact: No first aid should be needed. If contact with contents occurs, wash hands with soap and water.

Eye contact: No first aid should be needed. If contact occurs, flush eyes with plenty of water. Obtain medical attention if irritation persists.

Ingestion: No first aid should be needed. C-urea is excreted in the urine with a half-life of approximately 12 hours. The capsules produces radiation exposure equal to 24 hours of
normal background. In animal experiments, such low doses of radiation do not carry measurable risk.

**Most Important symptoms and effects, both acute and delayed:** None expected under normal conditions of use. If capsule is broken and contact occurs, may cause mild eye irritation.

**Indication of any immediate medical attention and special treatment needed:** None required.

### 5. FIRE-FIGHTING MEASURES

**Suitable (and unsuitable) Extinguishing Media:** Use media suitable for surrounding materials.

**Specific Hazards Arising from the Chemical:** None.

**Hazardous Combustion Products:** Combustion may produce carbon and nitrogen oxides.

**Special Protective Equipment and Precautions for Fire-fighters:** None required.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment, and Emergency Procedures:** Wear appropriate protective clothing and equipment.

**Environmental Precautions:** Report releases as required by local and federal regulations.

**Methods and Materials for Containment and Cleaning Up:** Pick up intact capsules and place into an appropriate container for disposal. If capsules are broken, wear nitrile gloves and sweep up material. Place into an appropriate container for disposal.

### 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** Avoid contact with eyes, skin and clothing. Wash thoughtly after handling.

**Conditions for Safe Storage, including any Incompatibilities:** Store in accordance with package insert or product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure limit(s)**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Exposure limit(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-hazardous ingredients (as PNOC)</td>
<td>5 mgm³ TWA OSHA PEL (respirable fraction)</td>
</tr>
</tbody>
</table>
15 mg/m³ TWA OSHA PEL (total dust)

14C Urea

None established

**Appropriate Engineering Controls:** No special ventilation normally required.

**Individual Protection Measures, such as Personal Protective Equipment:**

**Respiratory Protection:** No personal respiratory protective equipment normally required.

**Protective Gloves:** None required for normal use. If capsules, wear latex or nitrile gloves to avoid skin contact.

**Eye Protection:** None required for normal use. If capsule is broken and contact may occur, wear chemical safety goggles to avoid contact.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance and Odor</td>
<td>Clear hard gelatin capsule</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling point/range</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting point/range</td>
<td>133-135°C (271.4-275°F)</td>
</tr>
<tr>
<td>Relative Density (water=1)</td>
<td>1.335</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor density (air=1)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble</td>
</tr>
<tr>
<td>pH</td>
<td>Not available</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water):</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation Rate (Butyl acetate=1)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available</td>
</tr>
<tr>
<td>Volatile Organic Carbon Compounds (VOC) (g/L)</td>
<td>Not available</td>
</tr>
<tr>
<td>Flashpoint</td>
<td>None.</td>
</tr>
<tr>
<td>Flammable Limits in Air % by Volume:</td>
<td>LEL (Lower): Not applicable</td>
</tr>
<tr>
<td></td>
<td>UEL (Upper): Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature:</td>
<td>None.</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Other Information:

| Radiological Half-life: 5730 years | Maximum Effective Dose Equivalent: 0.3 mrem/mCi |

10. STABILITY AND REACTIVITY

Reactivity: Not reactive.

Chemical Stability: Stable at ambient temperature and pressure.

Possibility of Hazardous Reactions: None currently known.

Conditions to Avoid: None currently known.

Incompatible Materials: Strong oxidizing agents.

Hazardous Decomposition Products: Carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Symptoms/Effects of Overexposure:
The capsules produces radiation exposure equal to 24 hours of normal background. In animal experiments, such low doses of radiation do not carry measurable risk.

Inhalation: No adverse effects expected.

Skin contact: No adverse effects expected.

Eye contact: No adverse effects expected under normal use conditions. If capsules are broken, dust may cause mild eye irritation.

Ingestion: No adverse effects are expected. If ingestion occurs, $^{14}$C-urea that is not hydrolyzed in the stomach is excreted in the urine with a half-life of 12 hours. About 10% of the $^{14}$C remains in the body for 72 hours with a biological half-life of 40 days.

Chronic toxicity: None currently known.

Carcinogenicity Data: None of the components of this product is listed as a carcinogen by IARC, NTP, US OSHA or the EU CLP Annex VI.

Reproductive Toxicity: No data available.

Numerical Measures of Toxicity:
Non-hazardous Ingredients: Oral rat LD50 >5,000 mg/kg
$^{14}$C Urea: Oral rat LD50 >14,300 mg/kg.

12. ECOLOGICAL INFORMATION

Ecotoxicity: No data is currently available.

Persistence and Degradability: No data is currently available.

Bioaccumulative Potential: No data is currently available.
Mobility in Soil: No data is currently available.

Other Adverse Effects: None currently known.

13. DISPOSAL CONSIDERATIONS
Dispose in accordance with all state, local and federal regulations.

14. TRANSPORT INFORMATION
US DOT Shipping Description: Not regulated
IATA Shipping Description (Air): Not regulated
IMDG Shipping Description (Vessel): Not regulated

15. REGULATORY INFORMATION
US Regulations
EPA Toxic Substances Control Act (TSCA): All of the components of this product are listed on the TSCA Inventory or exempted from TSCA.
SARA 302 Listed Chemicals: None.
SARA 311/312 Hazard Categories: Not Hazardous
SARA 313 This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under the SARA Section 313 (40 CFR 372): None.
California Proposition 65: This product does not contain chemicals listed per the Safe Drinking Water and Toxic Enforcement Act of 1986.

16. OTHER INFORMATION
Date Prepared: 5/13/16
HMIS Rating: Health 0 Fire 0 Physical Hazard 0

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