Material Safety Data Sheet

OneStep PSA RapiDip™ InstaTest
For in-vitro diagnostic use only

SECTION 1. Company Identification

Product name: OneStep PSA RapiDip™ InstaTest
Catalog No.: 13080-1-44
Synonyms: N/A
Form: Rapid test kit for in vitro Diagnostic
Kit Storage: Room temperature

Company: Diagnostic Automation Inc.
Address: 21250 Califa St, Suite 102 & 116, Woodland Hills, CA 91367, USA.
Website: www.rapidtest.com
Phone: 818-591-3030
Fax: 818-591-8383
E-mail: onestep@rapidtest.com

Emergency phone: Contact your local Emergency Health Provider.

SECTION 2. Hazards Identification

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable
Chemical Ingredient Chemical Data / Information
Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008
The product does not need to be labelled in accordance with EC directives or respective national laws.
Hazard pictograms and Signal word: No
Hazardous components for labeling: No
Hazard statements: No
Precautionary statements: No

2.3 Other hazards

At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].

SECTION 3. Composition Information

This product is a mixture.
### Hazardous Ingredients

<table>
<thead>
<tr>
<th>Hazardous Ingredients</th>
<th>CAS no.</th>
<th>EINECS no.</th>
<th>REACH Registration no.</th>
<th>Classification: Category codes/ Hazard statement</th>
<th>W/W%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)</td>
<td>55965-84-9</td>
<td>N/A</td>
<td>Not available</td>
<td>Acute Tox. 3: H301-H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1: H400 Aquatic Chronic 1: H410</td>
<td>0.001%</td>
</tr>
</tbody>
</table>

Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1
Lowest specific concentration limits according to Table 3.1 Annex VI:
- Skin Corr. 1B: H314 C ≥ 0.6 %
- Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 %
- Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 %
- Skin Sens. 1; H317: C ≥ 0.015 %

### SECTION 4. First Aid Measures

#### 4.1 Description of first aid measures

- **After inhalation:**
  Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.

- **After skin contact:**
  Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.

- **After eye contact:**
  Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.

- **After ingestion:**
  If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

#### 4.2 Most important symptoms and effects (acute and delayed)

Not applicable.

#### 4.3 Indication of any immediate medical attention and special treatment needed

No data available.

### SECTION 5. Firefighting Measures

#### 5.1 Extinguishing media

Common fire extinguishing media (dry-chemical) should be used. Unsuitable media not investigated.

#### 5.2 Special hazards arising from the substance or mixture

Unknown.

#### 5.3 Advice for fire-fighters

Dry-chemical fire extinguishers.

### SECTION 6. Accidental Release Measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.
6.2 **Environmental precautions**
Avoid release to the environment.

6.3 **Methods and material for containment and cleaning up**
Broom.

6.4 **Reference to other sections**
Collect material and dispose of waste according to section 13.

### SECTION 7. Storage & Handling

7.1 **Precautions for safe handling**
**General hygiene measures:** Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use. Contaminated clothing and protective equipment must remove before entering eating areas.

7.2 **Conditions for safe storage, including any incompatibilities**
**Information about storage conditions:** Note the storage conditions on product packaging.
**Requirements for storage rooms and containers:** Store in a cool dry place.

7.3 **Specific end uses**
Rapid chromatographic immunoassay for the semi-quantitative detection of Prostate Specific Antigen in human whole blood, serum, or plasma specimen.

### SECTION 8. Exposure Controls/Personal Protection

8.1 **Control parameters**
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2 **Exposure controls**
8.2.1. **Appropriate engineering controls**
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 **Personal protective equipment**

| General protective and hygienic measures: | Adhere to good laboratory practices (GLP)  
| Wash hands before breaks and at the end of work. |
| Respiratory protection: | Not required. |
| Protective gloves: | Disposable gloves |
| Material of gloves: | Latex/natural rubber |
| Penetration time of glove material: | Gloves resistance is not critical when the product is handled according to the instruction for use. |
| Eye protection: | Safety glasses. |
| Body protection: | Lab coat |

8.3 **Environmental exposure controls**
There are no special precautions and measures. See sections 6 and 7.

### SECTION 9. Physical and Chemical Properties

9.1 **Information on basic physical and chemical properties**

| Physical state: | Solid |
| Color: | White appearance and some content of the test strip is purple |
| Odor: | Tasteless |
| Odor threshold: | Not established |
| Flash point: | Not established |
Self-ignition: Product is not known to be self-igniting
Danger of explosion: There is no substances in the kit could lead to the danger of explosion
Melting point: Not established
Boiling point: Not established
Vapor pressure: Not established
Density (20 °C): Not established
pH value at 20 °C: Not established
Solubility in water: The product almost could not solubilize in water

9.2 Other safety information
Not available.

SECTION 10. Stability and Reactivity

10.1 Reactivity
The product is stable in accordance with the recommended storage conditions.

10.2 Chemical stability
All the chemicals in the test kits are stable.

10.3 Possibility of hazardous reactions
Almost impossible.

10.4 Conditions to avoid
High humidity and temperatures out of 2-30 °C.

10.5 Incompatible materials
No.

10.6 Hazardous decomposition products
No.

SECTION 11. Toxicological Information

11.1 Information on toxicological effects (Mixture)

<table>
<thead>
<tr>
<th>Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity:</td>
<td>Quantitative date on the toxic effects of this product is not available.</td>
</tr>
<tr>
<td>Irritation:</td>
<td>Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.</td>
</tr>
<tr>
<td>Corrosivity:</td>
<td>Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.</td>
</tr>
<tr>
<td>Sensitization:</td>
<td>Contains a small volume of a very dilute, sensitizing preservative (ProClinit™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.</td>
</tr>
<tr>
<td>Repeated dose toxicity:</td>
<td>Not investigated.</td>
</tr>
<tr>
<td>Carcinogenicity:</td>
<td>Not investigated.</td>
</tr>
<tr>
<td>Mutagenicity:</td>
<td>Not investigated.</td>
</tr>
<tr>
<td>Toxicity for reproduction:</td>
<td>No reproductive toxic effect known.</td>
</tr>
</tbody>
</table>
SECTION 12. Ecological Information

12.1 Toxicity
No data available.

12.2 Persistence and degradability
No data available.

12.3 Bioaccumulative potential
No data available.

12.4 Mobility in soil
No data available.

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects
No data available.

SECTION 13. Disposal Considerations

13.1 Waste treatment methods

| Product: | Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information. |
| European waste catalog: | 18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection. |
| Packaging: | Disposal must be made in accordance with local waste management regulations. 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 informations. |

SECTION 14. Transport Information

14.1 UN proper shipping name
ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.2 Transport hazard class
ADR/RID: - IMDG: - IATA: -

14.3 Packing group
ADR/RID: - IMDG: -IATA: -

14.4 Environmental hazards
ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: NO
Marine Pollutant: NO

14.5 Special precautions for user
See sections 6-8.

14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Delivery will only be taken in suitable and regulatory approved packaging.
SECTION 15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
EU regulations: This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment
The mixture was not subjected to security assessment.

SECTION 16. Other Information

General information
The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user’s responsibility to determine the suitability of the information for their particular purposes.