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

|  |  |  |
| --- | --- | --- |
| **1.1** | **Product identifier** |  |
|  | Trade name | Pro Advantage HCG Pregnacy Tests |
|  | Reference No. | P080063, P080023, P080021 |
| **1.2** | **Relevant identified uses of the substance or mixture and uses advised against** |  |
|  | Identified use(s) | In vitro diagnostic reagent. For professional use only. |
| **1.3** | **Details of the supplier of the safety data sheet** |  |
|  | Company Identification | NDC, Inc.  407 New Sanford Road  LaVergne, TN 37086, USA |
|  | Telephone | 615-366-3230 |
|  |  |  |
| **1.4** | **Emergency telephone number** |  |
|  | Emergency Phone No. | ChemTel Inc. International access: + (0)1-813-248-0585  ChemTel Inc. Free phone (North America only): 1-(800)-255-3924 |

# SECTION 2: HAZARDS IDENTIFICATION

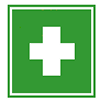
|  |  |  |
| --- | --- | --- |
| **2.1** | **Classification of the substance or mixture** | |
|  | **Regulation (EC) No. 1272/2008 (CLP)** | Eye Irrit. 2 |
|  | Hazard statement(s) | H319: Causes serious eye irritation. |
|  |  |  |
|  | **Directive 67/548/EEC & Directive 1999/45/EC** | Not classified as dangerous for supply/use. |
|  |  |  |
|  | **OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS** | 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. |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dangerous components:  EC Classification No. 1272/2008 / GHS   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Hazardous ingredient(s) | %W/W | EC No. | CAS No. | Classification code: Hazard statement(s) | | Sodium carbonate | 1 - 2 | 207-838-8 | 497-19-8 | Eye Irrit. 2; H319 | | Triton X100\* | 1 - 2 | - | 9002-93-1 | Acute Tox. 4; H302  Eye Dam. 1; H318  Aquatic Chronic 2; H411 | | Sodium azide\*\* | < 0.1 | 247-852-1 | 26628-22-8 | Acute Tox. 2; H300  Aquatic Acute 1; H400  Aquatic Chronic 1; H410  EUH032 |   EC Classification No. 67/548/EEC   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Hazardous ingredient(s) | %W/W | EC No. | CAS No. | EC Classification and Risk Phrases | | 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. |
|  | Ingestion | Wash out mouth with water. Consult a doctor. |
| **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 aparatus (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 / Irl OELV | |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **SUBSTANCE.** | **CAS No.** | **LTEL (8 hr TWA ppm)** | **LTEL (8 hr TWA mg/m³)** | **STEL (ppm)** | **STEL (mg/m³)** | **Note:** | | Sodium Azide | 26628-22-8 |  | 0.1 |  | 0.3 | Sk | | | | | |
|  | | 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  1-GLOVES | | 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/or an 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** | **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | Not applicable | |

# SECTION 15: REGULATORY INFORMATION

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | **15.1** | **Safety, health and environmental regulations/legislation specific for the substance or mixture** | In Vitro diagnostics medical devices directive 98/79/EC.  OSHA Hazard Communication Standard 29 CFR 1910.1200  Consumer Product Safety Regulations 16 CFR 1600  IVD Product Labelling 21 CFR 809 | |  | **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 | | | |
| LTEL | | | 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 | | | | |
| Xi | | | Irritant | | | | |
| Xn | | | Harmful. | | | | |
| T+ | | | Very toxic. | | | | |
| N | | | Dangerous for the environment. | | | | |
| **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. | | | |
|  | | | | | | |
| **Additional Information** | | | | | | |
|  | | Reason for update: | | | | Update in accordance with Regulation (EU) No 453/2010. Regulation (EC) No. 1272/2008 (CLP) & GHS  Changes to all sections. |
|  | | Supersedes: | | | | Version: 2 |

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