1. Product and Company Identification

Manufactured/Supplied by
MERCK & CO., INC.
One Merck Drive
Whitehouse Station, NJ 08889-0100
(908) 423-1000 (General Information Only)

Emergency Telephone Number:
1-908-423-6000 (24/7/365) English Only

Label Name
GARDASIL®

Chemical Name
Not available

Synonyms
Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant; HPV Vaccine.

Material Product Number
4045 - Carton of one 0.5 mL single-dose vial NDC 0006-4045-00
4045 - Carton of ten 0.5 mL single-dose vial NDC 0006-4045-41
4109 - Carton of six 0.5 mL single-dose prefilled syringe NDC 0006-4109-09

Intended Use
Vaccine indicated for the prevention of cancer, precancerous or dysplastic lesions, genital warts, and infection caused by the Human Papillomavirus (HPV) types 6, 11, 16 and 18.

2. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>Molecular Formula</th>
<th>Molecular weight</th>
<th>CAS Number</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV L1 VLPs</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
<td>0.024</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
<td>99.976</td>
</tr>
</tbody>
</table>

EC Label
Not classified.

3. Hazards Identification

Appearance
Cloudy white liquid.

Label Text
CAUTION!
VACCINE

Emergency Overview
No immediate hazard with intact vials.
Avoid direct contact with skin and eyes. Wash thoroughly after handling.

Potential Health Effects
See Section 11 for detailed information.

*** Continued on next page ***
4. **First Aid Measures**

   **Eye Contact**
   In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.

   **Skin Contact**
   In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse.

   **Inhalation**
   If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

   **Ingestion**
   Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

   **Notes to physician**
   Treat supportively and symptomatically.

   For additional guidance refer to the current prescribing information or the local poison control center.

5. **Fire Fighting Measures**

   **Flash Point**
   Not applicable

   **Flammable Limits (% in air)**
   Not applicable

   **Autoignition Temperature**
   Not available

   **Oxidizing Properties**
   Not available

   **Combustibility Information**
   Not available

   **Dust Explosivity Information**
   Not applicable

   **Shock Sensitivity**
   Not applicable

   **Fire/Explosion Hazards**
   None known.

   **Special Fire Procedures**
   No special procedures.

   **Extinguishing Media**
   In case of fire, use water spray (fog), foam, dry chemical, or CO$_2$.

   **Hazardous Decomposition Products**
   None known.

6. **Accidental Release Measures**

   **Personal Precautions**
   See Section 8 for Personal Protective Equipment. Contact emergency personnel. Keep unnecessary personnel away.

   **Methods for cleaning up**
   Contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. See Section 13 for Waste Disposal Information.
7. **Handling and Storage**

**Handling**
Avoid contact with skin and eyes. Wash thoroughly after handling.

**Storage**
Keep container tightly closed. Keep container in a cool, well-ventilated area.

8. **Exposure Controls/Personal Protection**

**Exposure Guidelines**

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA Permissible Exposure Limit (PEL)</th>
<th>ACGIH Threshold Limit Value (TLV)</th>
<th>Merck Exposure Control Limit (ECL) or PB-ECL Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV L1 VLPs</td>
<td>Not established</td>
<td>Not established</td>
<td>PB-ECL 2</td>
</tr>
<tr>
<td>Inactive ingredients</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
</tbody>
</table>

PB-ECL category is an internal Merck control band. Refer to control recommendations below.

**Engineering Controls**
None required when handling sealed vials.

Adequate ventilation should be provided if there is risk of aerosol formation.

**Personal Protective Equipment**

**Eye/Face Protection**
None required when handling sealed vials.

Safety glasses with side shields should be worn when handling bulk liquid formulation or filling vials.

**Skin Protection**
None required when handling sealed vials.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits).

**Respiratory Protection**
No respiratory protection required when handling bulk liquid formulation or sealed vials.

As an adjunct to engineering controls, use an approved, properly fitted, powered air purifying respirator, or respirator of equivalent or greater protection if the potential exists for exposure to airborne aerosols.

**Additional Protective Equipment**
Work uniform or laboratory coat.

9. **Physical and Chemical Properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Cloudy white liquid.</td>
</tr>
<tr>
<td><strong>Odor/Threshold Limit</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Boiling Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

*** Continued on next page ***
**Flammable Limits (% in air)**
\[ \text{Not applicable} \]

**Autoignition Temperature**
\[ \text{Not available} \]

**Solubility**
\[ \text{Not available} \]

**Partition Coefficient**
\[ \text{Not available} \]

**Specific Gravity**
\[ \text{Not available} \]

**Vapor Density**
\[ \text{Not available} \]

**Vapor Pressure**
\[ \text{Not available} \]

**Volatile Component**
\[ \text{Not available} \]

**10. Stability and Reactivity**

- **Stability**: Not available
- **Conditions to Avoid**: Not available
- **Incompatibility**: Not available
- **Hazardous Polymerization**: Not available
- **Hazardous Decomposition Products**: None known.

**11. Toxicological Information**

**Routes of Entry**
- **Ingestion**: No.
- **Inhalation**: Yes
- **Skin Contact**: No.

**Toxicity Data**

<table>
<thead>
<tr>
<th>Component</th>
<th>Test</th>
<th>Species</th>
<th>Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV L1 VLPs</td>
<td>Tolerability</td>
<td>Mouse</td>
<td>IM</td>
<td>No adverse effects except local irritation</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**Effects of Acute Exposure**
- **Eye contact**: Formulation may be irritating.
- **Skin contact**: Formulation may be irritating.
- **Inhalation**: Not available
- **Ingestion**: Not available

**Effects of Chronic Exposure**

GARDASIL is a vaccine indicated for the prevention of cancer, precancerous or dysplastic lesions, genital warts, and infection caused by the Human Papillomavirus (HPV) types targeted by the vaccine. GARDASIL contains L1 VLPs, which are proteins that resemble wild-type virions. Because the virus-like particles contain no viral DNA, they cannot infect cells or reproduce. The most commonly reported side effects include pain, swelling, itching and redness at the injection site, fever, nausea, dizziness, and vomiting. Syncope (fainting) with convulsions has also been reported. GARDASIL is contraindicated in individuals hypersensitive to any components of the vaccine. GARDASIL is not recommended for pregnant women.

It is not given chronically, but when injected 3 times in laboratory animals in a 13-week repeated dose intramuscular toxicity study, the primary effects were local irritation at the injection site and enlargement of the draining lymph nodes. There was also an antibody response as expected. Animal studies do not indicate

*** Continued on next page ***
direct or indirect harmful effects with respect to pregnancy, embryonic/fetal development, parturition or postnatal development. GARDASIL induced a specific antibody response against HPV Types 6, 11, 16, and 18 in pregnant rats following one or multiple intramuscular injections. Antibodies against all 4 HPV types were transferred to the offspring during gestation and possibly during lactation.

**Carcinogen Designation**
Not listed as a carcinogen by OSHA, NTP or IARC.

**Medical Conditions Aggravated by Overexposure:**
Not available

### 12. Ecological Information

**Environmental Effects**
Not available

**Ecotoxicity Data**

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Period</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV L1 VLPs</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>Inactive ingredients</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**Environmental Fate**
Not available

### 13. Disposal Considerations

**Waste Disposal Information**
Avoid contact of spilled material and runoff with soil and surface waterways. Dispose of or treat all spill residues including contaminated soils following all applicable regulations.

### 14. Transport Information

**Shipping Description**

| U.S. DOT                  | Not regulated. |
| IATA/ICAO                 | Not regulated. |
| IMO                       | Not regulated. |
| ADR/RID                   | Not regulated. |

### 15. Regulatory Information

**U.S. Federal Regulations**

**State Regulations**
Not available

**International Regulations**
Not classified as Dangerous according to the Dangerous Substances Directive (DSD).
16. **Other Information**

Revisions: Effects of Chronic Exposure

**Revision:** 12/28/2009.

**Date of Preparation** 26-Jun-2007

**Date of Previous Issue** 26-Jun-2007

**Validation Date** 12/28/2009.

**MSDS Coordinator:**

1-908-423-7903

Merck & Co., Inc.

One Merck Drive

Whitehouse Station, NJ 08889-0100

**Disclaimer:**

While this information and recommendations set forth are believed to be accurate as of the date hereof, MERCK & CO, INC. makes no warranty with respect hereto and disclaims all liability from reliance thereon.