

SAFETY DATA SHEET

PRODUCT NAME: GARDASIL®**Page: 1/6****Revision 28-Dec-2009**

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)

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

<u>Component</u>	<u>Molecular Formula</u>	<u>Molecular weight</u>	<u>CAS Number</u>	<u>Percent (%)</u>
HPV L1 VLPs	Not available	Not available	Not available	0.024
Inactive ingredients	Not available	Not available	Not available	99.976

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.

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 CO₂.

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

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

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

Appearance

Cloudy white liquid.

Odor/Threshold Limit

Not available

pH

Not available

Boiling Point

Not available

Melting Point

Not available

Flash point

Not applicable

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<u>Flammable Limits (% in air)</u>	Not applicable
<u>Autoignition Temperature</u>	Not available
<u>Solubility</u>	Not available
<u>Partition Coefficient</u>	Not available
<u>Specific Gravity</u>	Not available
<u>Vapor Density</u>	Not available
<u>Vapor Pressure</u>	Not available
<u>Volatility Component</u>	Not available

10. Stability and Reactivity

<u>Stability</u>	Not available
<u>Conditions to Avoid</u>	Not available
<u>Incompatibility</u>	Not available
<u>Hazardous Polymerization</u>	Not available
<u>Hazardous Decomposition Products</u>	None known.

11. Toxicological Information

<u>Routes of Entry</u>	Ingestion:	No.
	Inhalation:	Yes
	Skin Contact:	No.

Toxicity Data

<u>Component</u>	<u>Test</u>	<u>Species</u>	<u>Route</u>	<u>Result</u>
HPV L1 VLPs	Tolerability	Mouse	IM	No adverse effects except local irritation
Inactive Ingredients	Not available	Not available	Not available	Not available

Effects of Acute Exposure

<u>Eye contact</u>	Formulation may be irritating.
<u>Skin contact</u>	Formulation may be irritating.
<u>Inhalation</u>	Not available
<u>Ingestion</u>	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

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 DataComponentSpeciesPeriodResult

HPV L1 VLPs

Not available

Not available

Not available

Inactive ingredients

Not available

Not available

Not available

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 DescriptionU.S. DOT

Not regulated.

IATA/ICAO

Not regulated.

IMO

Not regulated.

ADR/RID

Not regulated.

15. Regulatory Information

U.S. Federal Regulations

Hazardous per OSHA Hazard Communication Standard criteria (29 CFR 1910.1200).

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.

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Disclaimer:

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