

## SAFETY DATA SHEET

Page 1 of 6 - Date of Issue: 15 November 2016

**IMPORTANT NOTICE** This Safety Data Sheet (SDS) is prepared by Seqirus Pty. Ltd. in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (February 2016). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.

---

### 1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

**Product Name** Gardasil®

**Other Names** Human Papillomavirus Quadrivalent (types 6, 11, 16 and 18), Vaccine, Recombinant: HPV Vaccine

**Manufacturer's Product Code** S30383, S30384, S30385, S30386

**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.

**Supplier Name** Seqirus Pty Ltd (ABN 26 160 735 035)

**Address** 63 Poplar Road, Parkville, Victoria 3052, Australia

**Telephone** +61 3 9389 2000

**Emergency Telephone** +61 3 9389 1984 (24hr)

---

### 2. HAZARDS IDENTIFICATION

**Not classified as a hazardous chemical according to Australian WHS Regulations**

**GHS Classification(s)** None Allocated

**Signal Word** No Signal Word

**Pictogram(s)** No Pictogram(s)

**Hazard Statement(s)** None Allocated

**Prevention statement(s)** None Allocated

**Response** None Allocated

**Storage** None Allocated

**Disposal** None Allocated

---

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Chemical Name:</i> HPV L1 VLPs	<i>CAS Number:</i> -	<i>Proportion:</i> <0.03%
Other non-hazardous ingredients	-	Up to 100%

---

### 4. FIRST AID MEASURES

<b>Eye</b>	In case of contact, flush eyes with plenty of water. Get medical attention if symptoms occur.
<b>Swallowed</b>	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 physician immediately.
<b>Skin</b>	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before use.
<b>Inhaled</b>	If inhaled remove to fresh air. If breathing is difficult, give oxygen. If not breathing give artificial respiration. Get medical attention if symptoms occur.
<b>First Aid Facilities</b>	Ensure water is available at point of use.
<b>Advice to Doctor</b>	Treat symptomatically.

---

### 5. FIRE FIGHTING MEASURES

<b>Fire/Explosion Hazard</b>	None known.
<b>Fire Extinguishing Media</b>	- Dry chemical powder - Water spray or fog - Foam - Carbon Dioxide
<b>Hazchem Code</b>	None allocated

---

### 6. ACCIDENTAL RELEASE MEASURES

<b>Minor Spills</b>	- Contain spilled material. - Use absorbent (or soil in the absence of other suitable material) - Scoop up material and place in a sealed, liquid-proof container for disposal.
---------------------	---

---

- 
- |                     |  |
|---------------------|--|
| <b>Major Spills</b> | <ul style="list-style-type: none"><li>- Contain material ensuring runoff does not reach a waterway.</li><li>- Place spilled material in an appropriate container for disposal.</li><li>- Minimise contact of spilled material with solid to prevent runoff to surface waterways.</li></ul> |
|---------------------|--|
- 

## 7. HANDLING AND STORAGE

- Avoid contact with skin and eyes.
  - Keep it where children cannot reach it.
  - Store at 2 to 8 degrees Celsius.
  - Do not freeze vaccine.
  - Protect the injection from light by keeping it in the original pack until it is time for it to be given.
  - Do not use after the expiry date on the label.
- 

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- |                             |  |
|-----------------------------|--|
| <b>Exposure Standards</b>   | No exposure limits set by SWA or ACGIH   |
| <b>Engineering Controls</b> | Adequate ventilation should be provided if there is a risk of aerosol formation.   |
| <b>Personal Protection</b>  | None is required when handling sealed vials. Safety glasses and protective gloves should be worn when handling bulk liquid formulation or filling vials. The choice of protection should be based on the job activity and potential for exposure to the eyes and face. |
- 

## 9. PHYSICAL AND CHEMICAL PROPERTIES

- |                                    |                      |
|------------------------------------|----------------------|
| <b>Appearance</b>                  | Cloudy, white liquid |
| <b>Odour</b>                       | Not determined       |
| <b>pH</b>                          | Not determined       |
| <b>Boiling Point/Melting Point</b> | Not determined       |
| <b>Vapour Pressure</b>             | Not determined       |
| <b>Vapour Density</b>              | Not determined       |
| <b>Specific Gravity</b>            | Not determined       |
| <b>Flashpoint</b>                  | Not determined       |
| <b>Flammability Limits</b>         | Not determined       |
| <b>Solubility in Water</b>         | Not determined       |
-

---

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not available
<b>Stability</b>	Not available
<b>Decomposition Products</b>	None known

---

## 11. TOXICOLOGICAL INFORMATION

<b>Toxicity Data</b>	HPV L1 VLPs- in mouse- no adverse effects except local irritation
<i>Effects of Acute Exposure</i>	
<b>Eye</b>	Formulation may be irritating
<b>Swallowed</b>	Not available
<b>Skin</b>	Formulation may be irritating
<b>Inhaled</b>	Not available
<b>Chronic Health Effects</b>	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. 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 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.

---

## 12. ECOLOGICAL INFORMATION

- No data available.

---

---

### 13. DISPOSAL CONSIDERATIONS

- Avoid contact of spilled material and runoff with soil and surface waterways.
  - Dispose of or treat any spills residues including contaminated soils following all applicable local regulations.
- 

### 14. TRANSPORT INFORMATION

**Not Classified as a dangerous good by the criteria of the ADG Code**

**UN Number** None allocated

**DG Class** None allocated

**Subsidiary Risk** None allocated

**Packing Group** None allocated

**Hazchem Code** None allocated

---

### 15. REGULATORY INFORMATION

**Poisons Schedule Number** Schedule 4 (S4) – Prescription only medicine

---

### 16. OTHER INFORMATION

**Last Revised** 15 November 2016

**Reason for Revision**

- Update to GHS requirements
- Update Business contact details
- Update Composition and Physical properties information
- Updated NOHSC to SWA

**Abbreviations**

SWA - Safe Work Australia  
GHS - Globally Harmonised System  
WHS - Work, Health and Safety  
ADG Code - Australian Dangerous Goods Code  
UN Number - United Nations Number  
DG Class - Dangerous Goods Class  
CAS Number - Chemical Abstract Service Number

**Contact Point**

Company Contact: +61 3 9389 1984 (24hr)  
Australian Poisons Information Centre, 24 hour service: 13 11 26  
Australian Police, Fire Brigade or Ambulance: 000  
  
New Zealand Poisons Information Centre, 24 hour service: 0800 764 766  
New Zealand Police, Fire Brigade or Ambulance: 111

---

Whilst the information contained in this document is based on data which, to the best of our knowledge, was accurate and reliable at the time of preparation, no responsibility can be accepted by us for errors and omissions. Users are advised to make their own determination as to the suitability of this information in relation to their particular purposes and specific circumstances. Since the information contained in this document may be applied under conditions beyond our control, we can accept no responsibility for any loss or damage by any person acting or refraining from action as a result of this information.

---