

**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.

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## 1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

<b>Product Name</b>	Rotateq
<b>Other Names</b>	Rotavirus vaccine, live, pentavalent
<b>Manufacturer's Product Code</b>	Rotateq (2mL pack) 80750101
<b>Use</b>	Vaccine to protect against rotavirus gastroenteritis
<b>Supplier Name</b>	Seqirus Pty Ltd (ABN 26 160 735 035)
<b>Address</b>	63 Poplar Road, Parkville, Victoria 3052, Australia
<b>Telephone</b>	+61 3 9389 2000
<b>Emergency Telephone</b>	+61 3 9389 1984 (24hr)

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## 2. HAZARDS IDENTIFICATION

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

<b>GHS Classification(s)</b>	None Allocated
<b>Signal Word</b>	No Signal Word
<b>Pictogram(s)</b>	No Pictogram(s)
<b>Hazard Statement(s)</b>	None Allocated
<b>Prevention statement(s)</b>	None Allocated
<b>Response</b>	None Allocated
<b>Storage</b>	None Allocated
<b>Disposal</b>	None Allocated

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Chemical Name:</i> Live Pentavalent Rotavirus	<i>CAS Number:</i> -	<i>Proportion:</i> <5%
Non hazardous Ingredients	-	Up to 100%

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### 4. FIRST AID MEASURES

<b>Eye</b>	Flush eye thoroughly with water for at least 15 minutes. If irritation occurs, seek immediate medical attention.
<b>Ingestion</b>	DO NOT induce vomiting. Wash out mouth thoroughly with water and give plenty of water to drink.
<b>Skin</b>	Remove contaminated clothing. Wash affected areas thoroughly with soap and water. Seek medical attention in event of irritation.
<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.

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### 5. FIRE FIGHTING MEASURES

<b>Fire/Explosion Hazard</b>	None known
<b>Fire Extinguishing Media</b>	- Water spray - Carbon dioxide (CO <sub>2</sub> ) - Powder - Foam
<b>Hazchem Code</b>	None allocated

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### 6. ACCIDENTAL RELEASE MEASURES

<b>Minor Spills</b>	- Contain spilled material - Use absorbent (or soil, in absence of other suitable material) - Scoop up material and place in a sealed, liquid-proof container for disposal - Disinfect the affected area with 70% ethanol or a freshly made 10% bleach solution
<b>Major Spills</b>	- Contain material ensuring runoff does not reach a waterway - Place spilled material in an appropriate container for disposal - Minimise contact of spilled material with soil to prevent runoff to surface waterways - Disinfect the affected area with 70% ethanol or a freshly made

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10% bleach solution

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## 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.
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## 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. None required when handling sealed vials.
<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.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Pale yellow clear liquid that may have a pink tint
<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

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## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not available
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**Stability** Not available

**Decomposition Products** None known

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## 11. TOXICOLOGICAL INFORMATION

**Eye** Not available

**Ingestion** Not available

**Skin** Not available

**Inhaled** Not available.

**Chronic Health Effects** This compound is a live oral pentavalent vaccine indicated for vaccination against rotavirus gastroenteritis in infants and children caused by serotypes G1, G2, G3, G4 and G-serotypes that contain P1A[8].

The vaccine is generally well tolerated. Diarrhoea, vomiting, pyrexia and nasopharyngitis occurred slightly more frequently in vaccine recipients.

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## 12. ECOLOGICAL INFORMATION

- No data available.
  - For good environmental practice avoid discharge to waterways.
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## 13. DISPOSAL CONSIDERATIONS

- Avoid contact of spilled material and run off with soil and surface waterways.
  - Dispose or treat all spill residues, including contaminated soil, in accordance with state land and waste management authority.
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## 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

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**15. REGULATORY INFORMATION**

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

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**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

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