

**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

**Product Name** Vivotif<sup>®</sup> Oral

**Other Names** Oral typhoid vaccine

**Manufacturer's Product Code** 04180803

**Use** For active immunisation against typhoid

**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)

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## 2. HAZARDS IDENTIFICATION

**Not classified as a hazardous chemical according to SWA**

**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

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Chemical Name:</i> Salmonella typhi strain Ty21a Berna Bacteria	<i>CAS Number:</i> -	<i>Proportion:</i> At least 2000 million live bacteria per capsule
Ethylene Glycol	107-21-1	<1.5mg per capsule
Other Non-Hazardous Ingredients	-	Up to 100%

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### 4. FIRST AID MEASURES

<b>Eye</b>	Hold eye open, wash with clean, gently running water for at least 15 minute. Seek medical attention in event of irritation.
<b>Swallowed</b>	Wash out mouth thoroughly with water. If exposed subject is fully conscious, give plenty of water to drink. If irritation or discomfort develops seek medical attention.
<b>Skin</b>	Remove contaminated clothing. Flush exposed area with water.
<b>Inhaled</b>	If powder is present remove person from exposure. If breathing is difficult or ceases, ensure and maintain ventilation, obtain medical attention and give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or if hypersensitivity occurs
<b>Aggravated Medical Conditions</b>	In individuals hypersensitive to Vivotif <sup>®</sup> Oral, may precipitate an acute allergic reaction.  Symptoms of an allergic reaction may include shortness of breath; swelling of the face, lips, tongue, or other parts of the body; skin rash, itching or hives.
<b>Advice to Doctor</b>	Treat symptomatically.

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### 5. FIRE FIGHTING MEASURES

<b>Fire/Explosion Hazard</b>	Toxic gases may be emitted from fires involving large amounts (multiple packages/pellets) of this product and its packaging, therefore self-contained breathing apparatus and full protective equipment are recommended for fire fighters. Where possible, contain and collect fire-fighting water for later disposal.
<b>Fire Extinguishing Media</b>	No restrictions
<b>Hazchem Code</b>	None allocated

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## 6. ACCIDENTAL RELEASE MEASURES

- |                     |  |
|---------------------|--|
| <b>Minor Spills</b> | <ul style="list-style-type: none"><li>- Clean up spill immediately.</li><li>- Wear protective gloves.</li><li>- Take care to avoid excessive dust during clean up.</li><li>- If dust is present wear a minimum P1 filter grade dust mask and safety glasses.</li><li>- Place spilled material in clean, dry, sealed container for disposal.</li><li>- Wash area with copious amounts of water.</li></ul> |
| <b>Major Spills</b> | <ul style="list-style-type: none"><li>- Wear protective gloves and safety glasses.</li><li>- Take care to avoid creating excessive dust during clean up.</li><li>- If dust is present wear a minimum P1 filter grade dust mask.</li><li>- Place spilled material in clean, dry, sealed container for disposal.</li><li>- Wash area with copious amounts of water.</li></ul>                              |

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## 7. HANDLING AND STORAGE

- Store between 2°C and 8°C in dry conditions- do not freeze.
- Store as per Schedule 4 pharmaceutical.
- Protect from light.
- Limit all unnecessary personal contact.
- Avoid puncturing or crushing capsules.

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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> | None under normal operating conditions.   |
| <b>Personal Protection</b>  | No special equipment needed when handling unbroken capsules. Otherwise, for potentially moderate exposure or if the powder has spilled from damaged capsules: <ul style="list-style-type: none"><li>- Protective gloves</li><li>- Safety glasses</li><li>- P1 grade dust mask</li></ul> |

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

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|-------------------|--|
| <b>Appearance</b> | Powder contained within a salmon/white bicolour gelatine capsule |
| <b>Odour</b>      | Odourless  |
| <b>pH</b>         | Not determined   |

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<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 known to be incompatible with any other material.
<b>Stability</b>	Stable under anticipated storage and handling conditions (refer section 7).
<b>Decomposition Products</b>	Not determined.

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## 11. TOXICOLOGICAL INFORMATION

<b>Eye</b>	May cause irritation following direct contact with powder.
<b>Swallowed</b>	<p>Adverse reactions are infrequent and generally mild. In the reported trials the following adverse effects were noted - constipation, abdominal cramps, diarrhoea, nausea, vomiting, anorexia, fever, headache and urticarial exanthema.</p> <p>In hypersensitive individuals, may precipitate an acute allergic reaction. Severe allergic reactions will usually occur within the first few hours of ingestion. Symptoms of an allergic reaction may include shortness of breath; swelling of the face, lips, tongue, or other parts of the body; skin rash, itching or hives.</p>
<b>Skin</b>	No adverse health effects expected.
<b>Inhaled</b>	Not an expected route of exposure unless powder is present. May cause mild irritation to respiratory tract.
<b>Chronic Health Effects</b>	No chronic health effects known.

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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

- In accordance with state land and waste management authority.
  - Dispose via a licensed waste facility.
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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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