

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 (June 2023). 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 VAQTA®

Other Names

Manufacturer's Product Code 80600001 VAQTA Adult 1.0mL x 1 Syringe Hepatitis A Vaccine Inact 1.0mL VAQTA (Adult) Syringe

80600002 VAQTA (Adult) Vial Hepatitis A Vacc Inact 1.0mL

Use Hepatitis A Vaccine

Manufacturer's Name MERCK & CO., INC.

Address One Merck Drive, Whitehouse Station, NJ 08889-0100 USA

Telephone (908) 423-1000

Emergency Telephone 1-908-423-6000

Supplier's Name Seqirus Pty. Ltd. (ABN 26 160 735 035)

Address 63 Poplar Road, Parkville, Victoria 3052, Australia

Telephone +61 03 9389 1911

Emergency Telephone +61 03 9389 1984 (24hr)

2. HAZARDS IDENTIFICATION

Not classified as hazardous according to the criteria of the 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>	<i>CAS Number:</i>	<i>Proportion:</i>
Hepatitis A protein	-	< 0.01 %
Other non-hazardous ingredients	-	Up to 100%

4. FIRST AID MEASURES

- Eye** In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. 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.
- Skin** 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.
- Inhaled** If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
- Advice to Doctor** Treat supportively and symptomatically. For additional guidance refer to the current prescribing information or the local poison control centre.

5. FIRE FIGHTING MEASURES

- Fire/Explosion Hazard** None known
- Fire Extinguishing Media** In case of fire, use water spray (fog), foam, dry chemical, or CO₂.
- Hazchem Code** Not applicable

6. ACCIDENTAL RELEASE MEASURES

- Minor Spills** Contain spilled material. 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.
- Major Spills** Contain spilled material. 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.

7. HANDLING AND STORAGE

Avoid direct contact with skin and eyes. Wash thoroughly after handling.

Keep container tightly closed. Store vials at 2-8°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards No exposure limits set by SWA or ACGIH.

Engineering Controls None required when handling sealed vials.
Adequate ventilation should be provided if there is risk of aerosol formation.

Personal Protection 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 - Additional body garments should be used based upon the task being performed (e.g., gloves, 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 Slightly opaque white suspension

Odour Not available

pH Not available

Boiling Point/Melting Point Not available

Vapour Pressure Not available

Vapour Density Not available

Specific Gravity Not available

Flashpoint Not applicable

Flammability Limits Not applicable

Solubility in Water No available

10. STABILITY AND REACTIVITY

Reactivity Not available

Stability Not available

Decomposition Products Not known

11. TOXICOLOGICAL INFORMATION

Skin Non-irritating to the skin.

Eye Non-irritating to the eyes.

Inhalation Not available

Ingestion Not available

Chronic Health Effects This compound is a vaccine indicated for immunization against infection caused by hepatitis A virus. VAQTA has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility. In clinical trials, injection-site complaints were the most frequently reported complaints. Other side effects reported in clinical trials included fatigue, fever, stomach pain, throat inflammation, muscle pain, diarrhoea, vomiting, menstruation disorder, and headache. Not listed as a carcinogen by OSHA, NTP or IARC.

12. ECOLOGICAL INFORMATION

Not available

13. DISPOSAL CONSIDERATIONS

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

Not classified as a dangerous good by the criteria of the ADG Code

UN Number Not applicable

Proper Shipping Name Not applicable

Transport Hazard Class Not applicable

Packing Group Not applicable

Hazchem Code Not applicable

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Date of Issue 20 March 2017
Reason for update Update SDS Code of Practice version
Periodic Review

Abbreviations

SWA Safe Work Australia
WHS Work, Health and Safety
GHS Globally Harmonised System
ACGIH American Conference of Governmental Industrial Hygienists
ADG Code Australian Dangerous Goods Code
UN Number United Nations Number
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

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