

SAFETY DATA SHEET

PRODUCT NAME: VAQTA®

Page: 1/6

Revision 14-Oct-2008

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)

Emergency Telephone Number:

1-908-423-6000 (24/7/365) English Only

Label Name

VAQTA®

Chemical Name

hepatitis A vaccine

Synonyms

Not available

Material Product Number4831 - Pediatric/Adolescent Formulation 0.5 mL single-dose vial
(NDC 0006-4831-00)4831 - Pediatric/Adolescent Formulation 0.5 mL single-dose vial
in a box of 10 single-dose vials
(NDC 0006-4831-41)4095 - Pediatric/Adolescent Formulation 0.5 mL single-dose
pre-filled Luer Lock syringe, perassembled with with UltraSafe
Passive delivery system in a box of 6 single-dose prefilled
syringes with six one-inch 23 gauge needles provided separately
in the package. (NDC 0006-4095-06)4841 - Adult Formulation 1 mL single-dose vial (NDC
0006-4841-00)and 1 mL single-dose vial in box of 10 single-dose vials
(NDC 0006-4995-41)4096 - Adult Formulation 1 mL single-dose pre-filled Luer Lock
syringe, preassembled with UltraSafe Passive delivery system
with a one-inch 23 gauge needle provided separately in the
package.

(NDC 0006-4096-31)

4096 - Adult Formulation 1 mL single-dose pre-filled Luer Lock
syringe, preassembled with UltraSafe Passive delivery system in a
box of 6 single-dose prefilled syringes with six one-inch 23 gauge
needles provided separately in the package. (NDC 0006-4096-06)Intended UseVaccine indicated for immunization against infection caused by
hepatitis A virus.

2. Composition/Information on Ingredients

<u>Component</u>	<u>Molecular Formula</u>	<u>Molecular weight</u>	<u>CAS Number</u>	<u>Percent (%)</u>
Hepatitis A protein	Not available	Not available	Not available	<0.01
Inactive ingredients	---	Not available	---	99.9

*** Continued on next page ***

EC Label Not classified as Dangerous according to the Dangerous Substances Directive (DSD).

3. Hazards Identification

Appearance Slightly opaque white suspension

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, immediately flush eyes with plenty of water for at least 15 minutes. 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. Follow all fire fighting procedures (Section 5).

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

Storage

Keep container tightly closed. Store vials at 2-8°C (36-46.4°F).

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>
Hepatitis A protein	Not established	Not established	Not established
Inactive ingredients	Not available	Not available	Not available

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

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

<u>Appearance</u>	Slightly opaque white suspension
<u>Odor/Threshold Limit</u>	Not available
<u>pH</u>	Not available
<u>Boiling Point</u>	Not available
<u>Melting Point</u>	Not available
<u>Flash point</u>	Not applicable
<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>
Hepatitis A protein	Not available	Not available	Not available	Not available
Inactive ingredients	Not available	Not available	Not available	Not available

Effects of Acute Exposure

<u>Eye contact</u>	Non-irritating to the eyes.
<u>Skin contact</u>	Non-irritating to the skin.
<u>Inhalation</u>	Not available
<u>Ingestion</u>	Not available

Effects of Chronic Exposure

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, diarrhea, vomiting, menstruation disorder, and headache.

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 Data

Component

Species

Period

Result

Hepatitis A protein

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 Description

U.S. DOT

Not regulated.

IATA/ICAO

Not regulated.

IMO

Not regulated.

ADR/RID

Not regulated.

15. Regulatory Information

U.S. Federal Regulations

Not 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:

10/14/2008.

Date of Preparation

2-Jul-2007

Date of Previous Issue

6-Aug-2008

Validation Date

10/14/2008.

MSDS Coordinator:

1-908-423-7903
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889-0100

Disclaimer:

While this information and recommendations set forth are believed to be accurate as of the date hereof, MERCK & CO, INC. makes no warranty with respect hereto and disclaims all liability from reliance thereon.