

SAFETY DATA SHEET

PRODUCT NAME: RotaTeq**Page:** 1/6**Revision** 4-Jun-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 RotaTeq

Chemical Name Not available

Synonyms Rotavirus vaccine, live, pentavalent

Material Product Number 4047 - RotaTeq 2mL

Intended Use Vaccine to protect against rotavirus gastroenteritis

2. Composition/Information on Ingredients

<u>Component</u>	<u>Molecular Formula</u>	<u>Molecular weight</u>	<u>CAS Number</u>	<u>Percent (%)</u>
Live pentavalent rotavirus vaccine	Not available	Not available	Not available	<5%
Inactive ingredients	Not available	Not available	Not available	>95%

EC Label This product is not classified according to the EU regulations.

3. Hazards Identification

Appearance Pale yellow clear liquid that may have a pink tint

Label Text CAUTION!
VACCINE

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 irritation occurs.

Skin Contact Wash with soap and water. Get medical attention if symptoms occur.

Inhalation If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention.

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 available

Autoignition Temperature

Not available

Oxidizing Properties

Not available

Combustibility Information

Not available

Dust Explosivity Information

Not available

Shock Sensitivity

Not available

Fire/Explosion Hazards

Not available

Special Fire Procedures

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

Extinguishing Media

In case of fire, use water spray (fog), foam, dry chemical, or CO₂.

Hazardous Decomposition Products

Not available

6. Accidental Release Measures

Personal Precautions

See Section 8 for Personal Protective Equipment Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures (Section 5).

Methods for cleaning up

If emergency personnel are unavailable, 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

Rotateq rotavirus vaccine, live should be stored and transported at 2-8 °C (36-46°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>
Live pentavalent rotavirus vaccine	Not available	Not available	Not established
Inactive ingredients	Not available	Not available	Not established

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. Wear appropriate splash goggles if there is a potential for direct contact with liquid splash, mists or aerosols. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with liquids, mists, or aerosols.

Skin Protection

None required when handling sealed vials.

Disposable chemical resistant gloves.

Respiratory Protection

No respiratory protection required when handling bulk liquid formulation or sealed vials.

Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. When handling a compound in solution, a cartridge/canister appropriate for the solution may also be needed.

Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.

Additional Protective Equipment

None required when handling sealed vials.

Work uniform or laboratory coat.

9. Physical and Chemical Properties

<u>Appearance</u>	Pale yellow clear liquid that may have a pink tint
<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 available
<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>	The product is stable.
<u>Conditions to Avoid</u>	Not available
<u>Incompatibility</u>	Not available
<u>Hazardous Polymerization</u>	Not available
<u>Hazardous Decomposition Products</u>	Not available

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>
Live pentavalent rotavirus vaccine	Not available	Not available	Not available	Not available

Effects of Acute Exposure

<u>Eye contact</u>	Not available
<u>Skin contact</u>	Not available
<u>Inhalation</u>	Not available
<u>Ingestion</u>	Not available

Effects of Chronic Exposure

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. Diarrhea, vomiting, pyrexia, and nasopharyngitis occurred slightly more frequently in vaccine recipients.

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Carcinogen Designation

Not listed as a carcinogen by OSHA, NTP or IARC.

Medical Conditions Aggravated by Overexposure:

Not available

12. Ecological InformationEnvironmental Effects

Not available

Ecotoxicity DataComponentSpeciesPeriodResult

Live pentavalent rotavirus vaccine

Not available

Not available

Not available

Environmental Fate

Not available

13. Disposal ConsiderationsWaste 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 InformationShipping DescriptionU.S. DOT

Not regulated.

IATA/ICAO

Not regulated.

IMO

Not regulated.

ADR/RID

Not regulated.

15. Regulatory InformationU.S. Federal Regulations

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: Material Product Number

Revision:

6/4/2008.

Date of Preparation

1-May-2008

Date of Previous Issue

Not applicable

Validation Date

6/4/2008.

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

Disclaimer:

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