

**ROTATEQ® Vaccine Agent Summary Sheet (VASS)
(Human-Bovine Reassortant Rotavirus, Live, Attenuated)**

**Health and Safety Summary Information for Employees Working with:
Human-Bovine Reassortant Rotavirus**

SECTION I-IDENTIFICATION

Organism: Human-bovine reassortant strain of rotavirus (WC3 bovine rotavirus backbone containing one or more human rotavirus RNA segments) (5).

Characteristics: The reassortant rotavirus is not capable of causing disease in adult humans.

Company Information: 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

SECTION II-HAZARD IDENTIFICATION

Vaccine protects against: Rotavirus infection. Transmission is likely fecal-oral, with possible contact or respiratory spread. Initial infection is characterized by vomiting and fever, followed by a watery diarrhea occasionally associated with severe dehydration and death in infants and young children < 2 years old. Secondary symptomatic cases among adult family contacts can occur, although subclinical infections occur frequently. Susceptibility is greatest between 6 and 24 months of age. By three years, most individuals have acquired rotavirus antibodies (4).

SECTION III-HEALTH HAZARDS

Special circumstances:

Immune Status: Changes in the immune system due to cancer or cancer therapy (radiation or chemotherapy), steroid use, tuberculosis, or diseases of the immune system (including HIV/AIDS) must be reported immediately to their occupational health group or personal physician, as appropriate. The US Advisory Committee on Immunizations Practices (ACIP) has recommended severely immunocompromised individuals not be exposed to live virus vaccines, as there is a risk of severe complications (1).

Pregnancy: Women who are considering pregnancy should consult with their occupational health group or personal physician, as appropriate, prior to conception. The wild type virus is not known to cross the placenta or cause congenital birth defects.

SECTION IV-MEDICAL

Medical Surveillance: There is no routine medical surveillance for persons with a healthy immune system working with the vaccine strain of rotavirus.

Medical risk for workers: The risk from exposure to the live vaccine virus to a healthy employee appears to be low to no risk, the same as being given the vaccine. For a pregnant employee, the risk to her and her unborn child appears to be low to no risk, but the risk cannot be quantified precisely.

**ROTATEQ® Vaccine Agent Summary Sheet (VASS)
(Human-Bovine Reassortant Rotavirus, Live, Attenuated)**

SECTION V-RECOMMENDED PRECAUTIONS

Containment/Vaccination Policy regarding this agent: Containment for human-bovine reassortant rotavirus is BSL1 (BSL1 containment is for organisms not considered to cause disease in healthy adult humans). Containment for Vero cells is BSL1 (BSL1 containment is for organisms not considered to cause disease in healthy adult humans).

SECTION VI-HANDLING INFORMATION

Spills: A spill clean-up SOP should be developed. In the event it is not available, the rotavirus is inactivated by 95% ethanol or phenolics such as Vesphene and LpH. A freshly made 10% bleach solution will also inactivate the virus, but can damage stainless steel. The standard procedure for any large spill in an open area is to leave the area for 30 min prior to returning to disinfect the area. Wear gloves, safety glasses, face mask or respirator (as allowed under national regulation), “bunny” suit, and shoe covers.

References

1. Centers for Disease Control and Prevention. Recommendations of the Advisory Committee on Immunization Practices (ACIP): Use of vaccines and immune globulins in persons with altered immunocompetence. MMWR **42**(No. RR-4). 1993.
2. Centers for Disease Control and Prevention. Update: Vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions. Recommendations of the Advisory Committee on Immunization Practices. MMWR **45**(No RR-12). 1996.
3. Estes, MK. Rotaviruses and their replication. In: *Fields Virology, 3rd Edition*. (B.N. Fields, D.M. Knipe, P.M. Howley, eds.) Lippincott-Raven, Philadelphia, 1996.
4. Heymann, DL, Ed. Rotaviral enteritis. In: *Control of Communicable Diseases Manual, 18th Ed.* Am. Public Health Assoc., 2008.
5. Prescribing Information, RotaTeq. Merck & Co., Inc. February 2009.

Disclaimer

While this information and recommendations 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.