

A Safety Data Sheet is not required for this product according to OSHA Regulation 29CFR 1910.1200(g).

A hazard evaluation has been conducted on the constituents in this product in accordance with OSHA's Hazard Communication Standard, 29 CFR 1910.1200(d). It has been determined that the product is not a hazardous chemical, and does not pose a physical or health hazard according to the guidelines set by OSHA's Hazard Communication Standard.

RECOMBIVAX HB® Vaccine Agent Summary Sheet (VASS) (Hepatitis B Vaccine (Recombinant))

Health and Safety Summary Information for Employees Working with: Hepatitis B Vaccine

SECTION I-IDENTIFICATION

Organism: Recombinant strain of *Saccharomyces cerevisiae* (yeast) containing a portion of the Hepatitis B genome coding for a viral surface antigen (HBsAg).

Characteristics:

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: Hepatitis B infection. Transmission of the wild type virus is via percutaneous or permucosal exposure to infectious body fluids (blood, serum-derived fluids, saliva, semen, vaginal fluids); commonly spread by contaminated needles, syringes or other IV equipment; contamination of wounds or lacerations; exposure of mucous membranes; or sexual contact. The infection is characterized by anorexia, abdominal discomfort, nausea, vomiting, rash, jaundice, and eventual liver failure. The incubation period for the virus is 45-180 days but an infected individual is infectious many weeks prior to the onset of symptoms and continue through their disease. Of those infected with the virus, 6-10% remain chronically infected. 5,000-6,000 deaths per year result from chronic HBV infection.

SECTION III-HEALTH HAZARDS

Special circumstances for workers handling vaccine:

Immune Status: Since the vaccine is prepared in yeast and contains only the single Hepatitis B surface antigen, a change in immune status will not alter susceptibility to the vaccine.

Pregnancy: As a good public health policy, women who are considering pregnancy should consult with Health Services prior to conception.

SECTION IV-MEDICAL

Medical Surveillance: There is no routine medical surveillance for persons working with the hepatitis B vaccine.

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.



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Medical risk for laboratory/production workers with Hepatitis B titers (circulating antibodies to virus): Only a single Hepatitis B gene is present in the yeast. There is no potential for Hepatitis B infection.

Medical risk for laboratory/production workers without Hepatitis B titers: Only a single Hepatitis B gene is present in the yeast. There is no potential for Hepatitis B infection.

SECTION V-RECOMMENDED PRECAUTIONS

Containment/Vaccination Policy regarding this agent: Containment for the vaccine follows Good Large Scale Practices (GLSP) since only a small portion of the viral genome is present. Staff members are recommended to have titers as part of Health Services' public health philosophy.

SECTION VI-HANDLING INFORMATION

Spills: Since no live organisms are present in the final formulated vaccine, no special biosafety procedures are required in the event of a spill. Spill cleanup is to be handled as per departmental SOP. If no SOP available, contain material using a spill pillow or absorbent material and dispose of according to departmental procedures. Soap and water can be used to clean up the area. Minimal personal protective equipment includes safety glasses, lab coat/work uniform, gloves and slip resistant shoe covers

References

Benenson, A, Ed. Hepatitis. In: *Control of Communicable Diseases Manual, 16th Ed.* Am. Public Health Assoc., 1995.

Medical Background Prescribing Information, Merck U.S. Medical and Scientific Affairs, 1999.

Murray, P, Ed. et al. *Manual of Clinical Microbiology, 6th Ed.* ASM Press, 1995.

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