

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.

VARIVAX® and ZOSTAVAX® Vaccine Agent Summary Sheet (VASS) (Varicella Virus Vaccine, Live [Oka/Merck])

Health and Safety Summary Information for Employees Working with: Attenuated Varicella Virus

SECTION I-IDENTIFICATION

Organism: Oka/Merck attenuated strain of varicella.

Characteristics: The Oka/Merck strain has been genetically weakened so it protects against the full effects of the disease while causing a generally mild reaction in under 5% of those vaccinated (8).

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: Varicella infection (chicken pox). The infection is characterized by fever (in children the fever is usually mild; in adults the fever may be severe) and a skin eruption that forms vesicles and leaves a granular scab. The lesions occur in successive crops and they tend to be more abundant on covered parts of the body. They may occur on the scalp, on mucous membranes of the mouth and respiratory tract and on the conjunctivae. The affected person is infectious from up to 5 days prior to the start of symptoms until approximately 5 days after the first crop of vesicles. Incubation period is 13 to 17 days (5).

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, organ transplant 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. Since the wild-type virus can damage the developing fetus (congenital varicella syndrome)(3,4,6), a registry has been established by Merck and the Centers for Disease Control and Prevention (CDC) to follow pregnant women inadvertently inoculated with the varicella vaccine or who became pregnant within 3 months of being vaccinated. To date, over 350 women have been followed, with no evidence of congenital varicella syndrome or birth defects linked to the vaccine, although the number of pregnancies is

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too small to be definitive (7). Fetuses of women with known immunity are not considered to be at risk for congenital varicella syndrome.

SECTION IV-MEDICAL

- **Workers in areas responsible for seed growth, propagation and storage and vaccine growth and propagation are required to have proof of titers or vaccination.** This is consistent with national guidelines and World Health Organization regulations for product protection.
- **All others are recommended to have titers** as part of a good public health philosophy.

Medical Surveillance: There is no routine medical surveillance for persons with a healthy immune system working with the vaccine strain of varicella. Changes in immune status or pregnancy must be communicated to their occupational health group or personal physician, as appropriate, immediately.

Medical risk for workers with varicella titers (circulating antibodies to virus): There are no known cases of infection of a person with a titer and a functioning immune system.

Medical risk for workers without varicella titers: 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 (2).

SECTION V-RECOMMENDED PRECAUTIONS

Containment/Vaccination Policy regarding this agent: Containment for attenuated varicella is BSL1 (BSL1 containment is for organisms not considered to cause disease in healthy adult humans). Containment for MRC-5 diploid fibroblasts is GLSP (Good Large Scale Practice is for organisms having built-in environmental limitations that permit optimum growth in the large-scale setting but limited survival without adverse consequences in the environment).

SECTION VI-HANDLING INFORMATION

Spills: A spill clean-up SOP should be developed. In the event it is not available, the enveloped varicella virus is easily inactivated. 70% ethanol, Vesphene and LpH are all capable of destroying the virus. 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): User of vaccines and immune globulins in persons with altered immunocompetence. MMWR **42**(No. RR-4). 1993.
2. Centers for Disease Control and Prevention. Prevention of Varicella: Recommendations of the Advisory Committee on Immunization Practices. MMWR **56**(No. RR-4). 2007.
3. Figueroa-Damian, R and Arredondo-Garcia, J. Perinatal outcome of pregnancies complicated with varicella infection during the first 20 weeks of gestation. Am J of Perinatology **14(10)**:411-414, 1997.

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4. Glick, M, and Goldman, HS. Viral infections in the dental setting. *JADA* **124**:79-86, 1993.
5. Heymann, A, Ed. Chickenpox/Herpes zoster. In: *Control of Communicable Diseases Manual, 18th Ed.* Am. Public Health Assoc., 2008.
6. Jantusch, B; and Sever, J. Viral Infections. In; *Occupational and Environmental Reproductive Hazards.* (M Paul, ed.) Williams & Williams, Maryland, 1993.
7. Long, S. Toddler-to mother transmission of varicella-vaccine virus: How bad is that? *J Pediatrics* **131**:10-12, 1977.
- 8 Prescribing Information, Varivax. Merck & Co., Inc. November 2008.

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