

Merck & Co., Inc.
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July 14, 2014



Our National Service Specialist, Maria Ricca, R.N., has referred your request for information regarding VARIVAX (varicella virus vaccine live (Oka/Merck)). Your inquiry concerned a Material Safety Data Sheet for VARIVAX.

The following information is provided as a professional service in response to your unsolicited inquiry. It is intended to provide you with a review of the available scientific literature and/or data that you requested. Merck does not recommend the use of its products in any manner other than as described in the prescribing information. Enclosed for your reference is the prescribing information for VARIVAX.

If you require further information or need to report suspected adverse reactions, please contact the Merck National Service Center at 1-800-672-6372.

If you would like to give feedback on the information that you have received, please connect to <http://www.surveymonkey.com/s/MerckPIRSurvey>. Thank you for your reply.

Sincerely,

A handwritten signature in black ink that reads "Mary Beth Tomeny".

Mary Beth Tomeny, RN, BSN, MHE
Senior Scientific Specialist
Merck Global Medical Information

Enclosures:
VARIVAX Prescribing Information

Case Number US14-023723

Information requested

Information requested by

This material is not listed as a carcinogen in the National Toxicology Program (NTP) Annual Report on Carcinogens, latest edition; the International Agency for Research on Cancer (IARC) Monographs, latest edition; or the Occupational Safety and Health Administration's 29 CFR 1910 subpart Z. In addition, it does not have an assigned Threshold Limit Value (TLV) in American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment, latest edition, and is not regulated by the Occupational Safety and Health Administration (OSHA). Furthermore, we are unaware of any published studies or literature that establishes that this material is hazardous under the Hazard Communication Standard as defined in 29 CFR 1910.1200 Sections (c) & (d). Hence, a Material Safety Data Sheet is neither required nor available.

Although a Material Safety Data Sheet is not available, relevant to your inquiry is the Vaccine Agent Summary Sheet (VASS) for VARIVAX, which contains health and safety summary information for employees working with attenuated varicella zoster virus.

**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).

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

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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.
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.

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6. Jantsch, 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.

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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