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.

ProQuad® Vaccine Agent Summary Sheet (VASS)

Measles, Mumps, Rubella and Varicella Virus Vaccine Live

Health and Safety Summary Information for Employees Working with: ProQuad®

SECTION I- IDENTIFICATION

Organisms: Attenuated Enders' Edmonston strain of measles virus, attenuated Jeryl Lynn[™] strain of mumps, attenuated Wistar Institute's RA 27/3 strain of rubella and attenuated Oka/Merck strain of varicella virus.

Characteristics: These viruses have been genetically weakened so they are not capable of causing disease in 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: Measles infection. Transmission of the wild type virus is via droplet spread or direct contact with nasal or throat secretions of infectious persons; less commonly by airborne spread or indirect contact with freshly infected articles. Measles is one of the most readily transmitted diseases. The infection is characterized usually by a mild fever (in children; in adults the fever may be severe), cough and a red, blotchy rash. The rash usually appears on the face 3-7 days after the fever starts and becomes generalized over the next 4-7 days. The affected person is infectious from the start of the fever until approximately 4 days after the rash appears. Incubation period is approximately 10 days (1).

SECTION III- HEALTH HAZARDS

Special circumstances for workers handling vaccine:

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.

Pregnancy: Women who are considering pregnancy should consult with their occupational health group or personal physician, as appropriate, prior to conception. Exposure to the vaccine, in the unlikely event it occurred, would be to the highly attenuated virus which is not capable of causing disease in humans and has not been associated with causing birth defects in women inadvertently

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receiving the vaccine while pregnant. Fetuses of women with known immunity (i.e., titers) are not considered to be at risk.

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 who come into contact with the vaccine 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 strains. Changes in immune status or pregnancy must be communicated to a person's occupational health group or personal physician, as appropriate, immediately.

Medical risk for workers with 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 titers: The risk from exposure to the live vaccine virus to a healthy worker 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.

SECTION V-RECOMMENDED PRECAUTIONS

Containment/Vaccination Policy regarding this agent: Containment for attenuated virus vaccines is BSL1 (BSL1 containment is for organisms not considered to cause disease in healthy adult humans).

SECTION VI-HANDLING INFORMATION

Spills: A SOP should exist for spill response and cleanup. In the event it is not available, these viruses are easily inactivated. 70% ethanol, Vesphene and LpH are all capable of destroying the viruses. 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, surgical mask or respirator (as allowed by national regulation), "bunny" suit, and shoe covers.

References

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.

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.

Centers for Disease Control and Prevention. Measles, Mumps, and Rubella-Vaccine use and Strategies for Elimination of Measles, Rubella, and Congenital Rubella syndrome and control of Mumps: Recommendations of the Advisory Committee on Immunization Practices. MMWR **47** (No. RR-8). 1998.

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