

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.

Vaccine Agent Summary Sheet (VASS)

Health and Safety Summary Information for Employees Working with:

Gardasil 9® Human Papillomavirus 9-valent Vaccine, Recombinant

Organism: Recombinant strain of *Saccharomyces cerevisiae* (yeast) containing a portion of the Human Papilloma virus (HPV) serotypes 6, 11, 16, 18, 31, 33, 45, 52 and 58 genome coding for viral surface proteins (L1).

Characteristics: Yeast, similar to Baker's yeast, is used to produce the viral surface proteins which act as antigens and produce immunity. This vaccine contains nine different serotypes of HPV antigen, but does not contain live Human Papilloma virus (HPV).

Company Information:

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SECTION II-HAZARD IDENTIFICATION

Vaccine protects against: Human papilloma virus infection. Transmission of the wild type virus is via direct contact. Human papilloma virus types 16 and 18, transmitted by sexual contact, are implicated in causing cervical cancer. Human papilloma virus types 6 and 11 are implicated in causing genital warts.

SECTION III-HEALTH HAZARDS

Special circumstances for workers handling vaccine:

Immune Status: Since the vaccine is prepared in yeast and contains only the papilloma virus surface proteins, a change in immune status will not alter susceptibility to the vaccine.

Pregnancy: Since no live virus is ever present, there is no known risk to women of childbearing age. 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 papilloma virus vaccine.

Medical risk for laboratory/production workers with or without HPV titers (circulating antibodies to virus): Only a single papilloma gene from each serotype is present in the yeast. There is no potential for human papilloma virus infection.

Gardasil 9® Human Papillomavirus 9-valent Vaccine, Recombinant 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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SECTION V-RECOMMENDED PRECAUTIONS

Containment/Vaccination Policy regarding this agent: Containment for the vaccine process follows Good Large Scale Practices (GLSP) since only a small portion of the viral genome is present. The vaccine consists of purified recombinant L1 capsid polypeptides which self assemble into virus-like particles that are absorbed onto alum adjuvant.

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. Malignant neoplasm of cervix uteri. In: *Control of Communicable Diseases Manual*, 16th Ed. Am. Public Health Assoc., 1995.

Kiviat, NB; and Koutsky, LA. Human papillomavirus. In: *Manual of Clinical Microbiology*, 6th Ed. (PR Murray, EJ Baron, MA Pfaller, FC Tenover, RH Tenover, eds.), ASM Press, 1995.

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