

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

PNEUMOVAX®23
(Pneumococcal Vaccine Polyvalent)

Health and Safety Summary Information for Employees Working with:
Streptococcus pneumoniae

SECTION I-IDENTIFICATION

Organism: Twenty three different strains of *Streptococcus pneumoniae* are grown, killed and processed to isolate their capsular polysaccharides. The production process begins with seed stock from wild type isolates of the bacteria.

Vaccine protects against: *Streptococcus pneumoniae* infection. Transmission of the bacterium is via droplet spread or direct contact with nasal or throat secretions of infectious persons. Person to person transmission is common, but illness among casual contacts is infrequent. The lung infection is characterized by a sudden onset of a shaking chill, fever, pleural (chest) pain, dyspnea (difficulty in breathing), tachypnea (rapid breathing) and a productive cough of "rusty" sputum.

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

Special circumstances for workers handling live *Streptococcus pneumoniae* bacteria:

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 Health Services.

Pregnancy: As a good public health policy, women who are considering pregnancy should consult with Health Services prior to conception. Pregnancy is not recognized to increase the risk of acquiring a *Streptococcus pneumoniae* infection and the bacterium is not a teratogenic agent.

Special circumstances for workers handling the final product: None

SECTION III-HEALTH HAZARDS

Medical Surveillance for workers handling live *Streptococcus pneumoniae* bacteria: Routine medical surveillance for persons with a healthy immune system working with the pneumococcus is not required. Prior to starting work in an area in which live bacteria is handled, an initial health assessment is required. Once an employee is working in an area where live bacteria is cultured or grown, changes in immune status must be communicated to Health Services immediately.

Medical risk for laboratory/production workers handling live *Streptococcus pneumoniae* bacteria: Inhalation of aerosol or direct contact of live bacteria to mucous membranes (eyes, nose, or mouth) or open

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

wounds on skin presents highest potential for infection. Contact with intact skin is unlikely to be a significant risk. Bacterium is capable of survival for days in the environment

First Aid: If the live bacterium contacts mucous membranes, cut or damaged skin, or is inhaled, wash affected areas and go to Health Services. If you develop symptoms of infection or have specific questions or concerns, you should consult with Employee Health Services or your personal physician.

Medical Surveillance for workers handling the final purified product: None

Medical risk for laboratory/production workers handling final purified product: None

SECTION V-RECOMMENDED PRECAUTIONS

Containment/Vaccination Policy regarding this agent: Containment for the live bacterium is BSL2 (BSL2 containment is for organisms capable of causing disease in healthy adult humans for which there usually is treatment). There is no biological risk from the killed bacterium or the purified polysaccharide.

- **All workers in areas handling the live bacterium are strongly recommended to have the vaccine** to minimize the risk of disease from exposure to the bacterium.
- **Workers in areas handling the final purified product:** None

SECTION VI-HANDLING INFORMATION

Spills during processing of live *Streptococcus pneumoniae* bacteria: Spill clean-up is to be handled as per departmental SOP. In the event it is not available, the production organism is easily inactivated. Vesphene and LpH are 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, appropriate respirator, "bunny" suit, and shoe covers.

Spills of the final purified product: 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. Pneumococcal pneumonia. In: *Control of Communicable Diseases Manual, 16th Ed.* Am. Public Health Assoc., 1995.

Maureen, P, Ed. *Occupational and Environmental Reproductive Hazards.* William & Wilkins. Maryland, 1993.

Laboratory Centre for Disease Control (Canada). *Streptococcus pneumoniae.* <http://www.hc-sc.gc.ca/hpb/lcdc/biosafety/msds/msds147e.html>