

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.

## VAQTA® Vaccine Agent Summary Sheet (VASS) (Hepatitis A Vaccine, Inactivated)

### Health and Safety Summary Information for Employees Working with: Live, Attenuated Hepatitis A Virus and Inactivated Virus Final Product

#### SECTION I-IDENTIFICATION

**Organism:** Hepatitis A virus (HAV) is grown in human MRC-5 diploid fibroblasts. This particular strain is derived by the passage of a proven attenuated strain (genetically weakened so it is not capable of causing disease in humans). The live, attenuated virus is inactivated with formaldehyde after purification. Once inactivated, live virus is no longer present

**Characteristics:** The final product has been inactivated with formaldehyde after purification. Once inactivated, live virus is no longer present

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#### SECTION II- HAZARD IDENTIFICATION

**Vaccine protects against:** Hepatitis A infection. Transmission of the wild -type virus is via the fecal-oral route; frequently by ingestion of contaminated food and water. In rare instances, transmission is by blood transfusion from a donor in the incubation period. The illness is characterized by an abrupt onset, fever, malaise, anorexia, nausea, abdominal discomfort, and jaundice after a few days, and eventual deterioration of the liver functions. The incubation period for the virus is 15-50 days; maximum infectivity occurs during the second half of the incubation period through the first few days after the onset of jaundice. Symptoms usually last less than 2 months, but may extend to 6 months. In the United States, approximately 33 million people have evidence of exposure to HAV (show some immunity to the virus).

#### SECTION III-HEALTH HAZARDS

**Special circumstances for workers handling the live vaccine virus:**

**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. 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. For HAV, the ACIP has also indicated that inactivated final product, used in the vaccine, is not considered a risk to immunocompromised individuals and the vaccine may be given to such individuals.

**Pregnancy:** Women who are considering pregnancy should consult with Health Services prior to conception. The wild-type virus has been associated with a slight risk for premature labor;

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however, risk of viral transmission from mother to fetus is rare. There is no congenital syndrome associated with the wild-type virus. Fetuses of women with known immunity are not considered to be at risk. The vaccine is inactivated after purification and the final product is not considered a significant risk. Pregnancy is not a contraindication for receiving the vaccine; however, the vaccine should be given to a pregnant woman only if clearly needed.

**Special circumstances for workers handling the inactivated virus / final product:** None

## SECTION IV-MEDICAL

**Medical Surveillance for workers handling the live virus:** There is no routine medical surveillance for persons with a healthy immune system working with the vaccine strain of Hepatitis A virus. Changes in immune status or pregnancy must be communicated to Health Services immediately.

**Medical Surveillance for workers handling the inactivated virus / final product:** None.

**Medical risk for laboratory or production workers with Hepatitis A titers (circulating antibodies to virus):** There are no known cases of hepatitis A infection of a person with a hepatitis A titer and a functioning immune system.

**Medical risk for laboratory or production workers with Hepatitis A titers (circulating antibodies to virus) handling the inactivated virus / final product:** None.

**Medical risk for laboratory/production workers without Hepatitis A titers handling the live virus:** The risk from exposure to the live attenuated vaccine virus to a healthy employee appears to be low to none, as the live virus was used in clinical trials as a potential vaccine and did not cause disease. 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. The inactivated vaccine is not contraindicated for pregnant women; however, the vaccine should be given to a pregnant woman only if clearly needed.

**Medical risk for laboratory or production workers without Hepatitis A titers handling the inactivated virus / final product:** None

## SECTION V-RECOMMENDED PRECAUTIONS

**Containment/Vaccination Policy regarding this agent:** Containment for live, attenuated Hepatitis A virus 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).

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

## SECTION VI-HANDLING INFORMATION

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**Spills during processing of live virus:** Spill clean-up is to be handled as per departmental SOP. In the event it is not available, the hepatitis A virus 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, face mask, "bunny" suit, and shoe covers.

**Spills of the inactivated vaccine virus / final 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

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