

Safety Data Sheet

1. Identification of the substance / preparation and company

- 1.1. PRODUCT NAME: Fluvirin[®] or
Inactivated Influenza Vaccine (Surface Antigen)
- 1.2. Address/ Phone No. Novartis Vaccines and Diagnostics
Gaskill Road,
Speke
Liverpool
L24 9GR
United Kingdom
Tel: 0151 705 5000
FAX: 0151 705 5018
- 1.3. Emergency Phone No. For specialist advice in an emergency,
Telephone 0151 705 5000

2. Composition / information on ingredients

- 2.1. The vaccine is a sterile parenteral for intramuscular use. It is a purified split-virus preparation propagated in embryonated chicken eggs. It does not contain any live virus particles and cannot cause influenza.
The active ingredients are purified proteins (haemagglutinin and neuraminidase) which have been isolated from the surfaces of three strains of influenza virus.
These strains chosen vary between Flu seasons although the differences present no difference to the handling of the product.
- 2.2. Fluvirin[®] vaccine is a suspension for injection supplied in a single dose 0.5ml syringe and 5ml multi-dose presentation. Each dose of the vaccine contains at least 15µg (15 micrograms) of protein of each recommended strain suspended in 0.5ml of water.
- 2.3. Thiomersal / Thimerosal is present as a preservative at 0.001% w/v in pre-filled syringes and 0.01% w/v in the multi dose vial formulation.
This is equivalent to 2.48µg and 24.8µg of mercury per 0.5 mL dose respectively.
- 2.4. Polymyxin, Neomycin, Betapropiolactone, and Nonylphenol Ethoxylate maybe present in trace quantities.

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3. Hazards Identification

- 3.1. The vaccine is potentially allergenic. Avoid contact with the material if allergic to Flu vaccine or to egg or chicken protein.
- 3.2. Avoid contact with the material if you have experienced any health problems after previous administration of an Influenza vaccine.
- 3.3. Avoid contact with the material if you are pregnant or breast-feeding.

4. First-Aid measures

- 4.1. For skin contact: wash thoroughly with soap and water.
- 4.2. For eye contact: irrigate thoroughly with water or eye wash fluid.
- 4.3. For accidental subcutaneous inoculation or wound contamination: Allow to bleed freely and cleanse. Seek medical attention if unusual symptoms occur e.g. high temperature, shivering, tiredness, headache, sweating, muscle pain, joint pain and generally feeling unwell.
Following vaccination (i.e. deliberate subcutaneous inoculation), fever, malaise, myalgia, headache and other systemic symptoms can occur, especially in young children who have had no previous exposure to influenza antigens. These reactions begin 6-12 hours after vaccination and persist for 1 to 2 days. In older persons, vaccination is not associated with higher rates of systemic symptoms.
- 4.4. For ingestion or inhalation: although significant problems are not expected it is advised to drink plenty of water following ingestion or inhalation.
Seek medical attention if unusual symptoms occur e.g. high temperature, shivering, tiredness, headache, sweating, muscle pain, joint pain and generally feeling unwell.
- 4.5. Very occasionally, a person who is extremely sensitive to some substance in the vaccine can suffer an allergic reaction following exposure. Under these circumstances, seek Immediate Medical attention. This includes Sensitivity to eggs; chicken feathers, chicken dander or Thiomersal.
Treatment for allergic / anaphylactic reactions includes adrenaline / epinephrine at 1:1000.

5. Fire-Fighting measures

- 5.1. All types of fire extinguisher are suitable.

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6. Accidental Release measures

- 6.1. Any spilt material is to be collected and disposed of as described in section 12.
- 6.2. Keep material away from water courses

7. Handling and Storage

- 7.1. Store refrigerated at 2°C to 8°C (36°F to 46°F). Keep away from direct light and do not freeze.
- 7.2. Wear rubber or nitrile gloves when cleaning up spillages / handling the material.
- 7.3. With the pre-filled syringe format there is a risk of needle-stick injury from un-sheathed needles and accidental subcutaneous inoculation.

8. Exposure controls / personal protection.

- 8.1. Wounds & abrasions on exposed skin to be protected with waterproof dressings.
- 8.2. Avoid direct exposure to the vaccine during pregnancy or whilst breast-feeding.

9. Physical and chemical properties

- 9.1. The vaccine is a slightly opalescent liquid.

10. Stability and reactivity

- 10.1. Fluvirin Influenza vaccine is stable when stored unopened at 2 to 8°C.
- 10.2. No major incompatibilities.

11. Toxicological information

- 11.1. The vaccine contains mercury at approximately 2.48µg per 0.5 mL dose (pre-filled syringe) and 24.8µg of mercury per 0.5 mL dose (multi dose vials).

12. Ecological information

- 12.1. The vaccine contains mercury and therefore should be prevented from entering watercourses or the atmosphere (by aerosol).

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13. Disposal considerations

- 13.1. Residues of mercury containing compounds are generally classified as special waste. Contact your local waste disposal authority for advice, or pass to a chemical disposal company.
- 13.2. Syringes (sharps) should be disposed of in accordance with local regulations. Contact your local waste disposal authority for advice.

14. Transport information

Not Applicable

15. Regulatory Information

- 15.1. Risk Phrases: Not Applicable
- 15.2. Safety Phrases: Not Applicable

16. Other information

- 16.1. This safety data sheet has been compiled in light of the requirements of the UK Chemicals (Hazard, Information and Packaging for Supply) Regulations 2002 which implement Commission Directive 91/155/EEC. However, the product is exempt from the requirements of the above regulations by virtue of it being intended for use as a medicinal product as defined in the Medicines Act 1968.
- 16.2. This safety data sheet does not constitute an assessment under the Control of Substances Hazardous to Health Regulations 2002.