

# Safety Data Sheet

## 1. Identification of the substance / preparation and company

- 1.1. PRODUCT NAME: Bulk Inactivated Influenza 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 5081
- 1.3. Emergency Phone No. For specialist advice in an emergency, Telephone 0151 705 5000

## 2. Composition / information on ingredients

- 2.1. The bulk material is a sterile, unpurified vaccine intermediate intended for use as a 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 a single variable strain of influenza virus ('a monobblend'). The actual strains vary between Flu seasons although the differences present no difference to the handling of the product.
- 2.2. Thiomersal / Thimerosal is present as a preservative at a maximum of 0.01%. This is equivalent to 49mg of mercury per litre.
- 2.3. Polymyxin, Neomycin, Betapropiolactone, Formaldehyde and Nonylphenol Ethoxylate maybe present in trace quantities.

## 3. Hazards Identification

- 3.1. The bulk fluid 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.
- 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 formulated vaccine can suffer an allergic reaction following exposure. It follows that the same is true for the bulk material. 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.

#### **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. The bulk material is usually contained within 100 or 200 litre stainless steel tanks. Handle with care and avoid collision or impact. Keep upright at all times.
- 7.2. Store refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze.
- 7.3. Wear rubber or latex gloves when cleaning up spillages / handling the bulk material.

#### **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 bulk material during pregnancy or whilst breast feeding.

## 9. Physical and chemical properties

9.1. A slightly opalescent liquid.

## 10. Stability and reactivity

10.1 The vaccine is stable when stored unopened at 2 °C to 8 °C (36 F to 46 F).

10.2 No major incompatibilities.

## 11 Toxicological information

11.1. Contains mercury at approximately 49mg of mercury per litre.

## 12. Ecological information

12.1. Contains mercury and therefore should be prevented from entering watercourses or the atmosphere (by aerosol).

## 13. Disposal considerations

13.1. Residues of mercury containing compounds are generally classified as special waste.

13.2. Contact your local waste disposal authority for advice, or pass to a chemical disposal company.

## 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 Substances Hazardous to Health Regulations 2002.

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