# Adjuvanted Inactivated Influenza Vaccine

**SDS Date: 20 Sep 2017**

## 1. Identification

**1.1. Product identifier**

| | |
|---|---|
| **Product Identity** | Adjuvanted Inactivated Influenza Vaccine (surface antigen) |
| **Alternate Names** | All egg-based Adjuvanted Inactivated Influenza Products manufactured or stored by Seqirus are covered by this Safety Data Sheet. |

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

| | |
|---|---|
| **Intended use** | See Technical Data Sheet. |
| **Application Method** | See Technical Data Sheet. |

**1.3. Details of the supplier of the safety data sheet**

| | |
|---|---|
| **Company Name** | Seqirus Vaccines<br>Gaskill Road, Speke<br>Liverpool L24 9GR<br>United Kingdom |

**Emergency**

| | |
|---|---|
| **24 hour Emergency Telephone No.** | 0151 705 5000<br>Emergency Product Information: +1 800 504-5434 |
| **Customer Service: Seqiris** | +1 610 878-4000 |

## 2. Hazard(s) identification

**2.1. Classification of the substance or mixture**

There are no ingredients in this product that are classified as hazardous and/or no hazardous ingredients above the cut-off GHS percentage

**2.2. Label elements**

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

**[Prevention]:**

No GHS prevention statements

**[Response]:**

No GHS response statements

**[Storage]:**

No GHS storage statements

**[Disposal]:**

No GHS disposal statements

## 3. Composition/information on ingredients

There are no ingredients in this product that are classified as hazardous and/or no hazardous ingredients above the cut-off GHS percentage.

Non Hazardous Ingredients:
Inactivated Influenza Virus Strains, 90 mcg/mL
MF-59 Adjuvant (172889-84-8), 50%
Calcium Chloride (10043-52-4), Trace
Neomycin, Trace
Polymyxin, Trace
Water for injection, balance

Other non-hazardous ingredients,
Thimerosal (54-64-8), 0.01% w/v **(multi-dose vial only)**

## 4. First aid measures

### 4.1. Description of first aid measures

| | |
|---|---|
| **General** | In all cases of doubt, or when symptoms persist, seek medical attention.<br>Never give anything by mouth to an unconscious person. Treat symptomatically. Cases of anaphylaxis may require treatment with adrenaline, oxygen, intravenous steroids and airway management including intubation. |
| **Inhalation** | Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth. |
| **Eyes** | Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention. |
| **Skin** | Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser. |
| **Ingestion** | DO NOT induce vomiting. Wash out mouth with water and give plenty of water to drink. If sensitive to eggs, feathers or other ingredients, seek medical attention immediately. |

### 4.2. Most important symptoms and effects, both acute and delayed

| | |
|---|---|
| **Aggravated Medical Conditions:** | Adjuvanted Inactivated Influenza Vaccines are prepared from virus grown in the allantoic cavity of embryonated eggs, therefore individuals with anaphylactic hypersensitivity to eggs and/or chicken feathers, neomycin, polymyxin or any other component of the vaccine should avoid direct contact with these vaccines. This would include persons whom upon ingestion of eggs develop swelling of the lips or tongue or experience acute respiratory distress or collapse. |

## 5. Fire-fighting measures

**5.1. Extinguishing media**

Not considered a significant fire risk

**5.2. Special hazards arising from the substance or mixture**

Hazardous decomposition: None known.

**5.3. Advice for fire-fighters**

None

**ERG Guide No.** Not Applicable

## 6. Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

Put on appropriate personal protective equipment (see section 8).

**6.2. Environmental precautions**

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

**6.3. Methods and material for containment and cleaning up**

Wear protective gloves and safety glasses when cleaning spills.
Minor Spill: Clean up spill immediately using absorbent paper towel. Wash area with copious amounts of water.
Major Spill: Contain and absorb spills using earth, sand or inert absorbent. Wash area with copious amounts of water.
Place spilled material in clean, dry, sealed container for disposal.

## 7. Handling and storage

**7.1. Precautions for safe handling**

Protect from light. Store as per Schedule 4 pharmaceutical.

**7.2. Conditions for safe storage, including any incompatibilities**

Handle containers carefully to prevent damage and spillage.

Transport and store between 2°C and 8°C.

Incompatible materials: No data available.

**7.3. Specific end use(s)**

No data available.

## 8. Exposure controls and personal protection

**8.1. Control parameters**

**There are no ingredients in this product which are classified as hazardous.**

**8.2. Exposure controls**

| | |
|---|---|
| **Respiratory** | None under normal conditions |
| **Eyes** | Protective safety glasses recommended |
| **Skin** | Protective gloves recommended. |
| **Engineering Controls** | None under normal conditions |
| **Other Work Practices** | Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse. |

## 9. Physical and chemical properties

| | |
|---|---|
| **Appearance** | A milky white liquid emulsion containing some sediment, which readily re-suspends upon shaking, in a pre-filled syringe with and without an attached needle, and multi-dose vial. |
| **Odor** | Odorless |
| **pH** | 6.9 - 7.4 |
| **Melting point / freezing point** | Not Determined |
| **Initial boiling point and boiling range** | Not Determined |
| **Flash Point** | Not Measured |
| **Evaporation rate (Ether = 1)** | Not Measured |
| **Flammability (solid, gas)** | Not Applicable |
| **Upper/lower flammability limits:** | Not Applicable |
| **Vapor pressure (Pa)** | Not Determined |
| **Vapor Density** | Not Determined |
| **Specific Gravity** | Not Determined |
| **Solubility in Water** | Aqueous solution |
| **Partition coefficient n-octanol/water (Log Kow)** | Not Measured |
| **Auto-ignition temperature** | Not Measured |
| **Decomposition temperature** | Not Measured |
| **Viscosity (cSt)** | Not Measured |

**9.2. Other information**

No other relevant information.

## 10. Stability and reactivity

**10.1. Reactivity**
Hazardous Polymerization will not occur.
**10.2. Chemical stability**
Stable under normal circumstances.
**10.3. Possibility of hazardous reactions**
No data available.
**10.4. Conditions to avoid**
No data available.
**10.5. Incompatible materials**
No data available.
**10.6. Hazardous decomposition products**
None known.

## 11. Toxicological information

**Acute toxicity**
There are no ingredients in this product which are classified as hazardous.

11.1 Thiomersal/Thimerosal is present as a preservative at 0.01% w/v **(in multi-dose vials only).**

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

| Classification | Category | Hazard Description |
|---|---|---|
| Acute toxicity (oral) | --- | Not Applicable |
| Acute toxicity (dermal) | --- | Not Applicable |
| Acute toxicity (inhalation) | --- | Not Applicable |
| Skin corrosion/irritation | --- | Not Applicable |
| Serious eye damage/irritation | --- | Not Applicable |
| Respiratory sensitization | --- | Not Applicable |
| Skin sensitization | --- | Not Applicable |
| Germ cell mutagenicity | --- | Not Applicable |
| Carcinogenicity | --- | Not Applicable |

| | | |
|---|---|---|
| Reproductive toxicity | --- | Not Applicable |
| STOT-single exposure | --- | Not Applicable |
| STOT-repeated exposure | --- | Not Applicable |
| Aspiration hazard | --- | Not Applicable |

## 12. Ecological information

**12.1. Toxicity**

No additional information provided for this product. See Section 3 for chemical specific data.
For good environmental practice, avoid discharge to waterways.

**Aquatic Ecotoxicity**

There are no ingredients in this product which are classified as hazardous.

**12.2. Persistence and degradability**

There is no data available on the preparation itself.

**12.3. Bioaccumulative potential**

Not Measured

**12.4. Mobility in soil**

No data available.

**12.5. Results of PBT and vPvB assessment**

This product contains no PBT/vPvB chemicals.

**12.6. Other adverse effects**

No data available.

## 13. Disposal considerations

**13.0. Waste treatment methods**

13.1 Observe all federal, state and local regulations when disposing of this substance.

13.2 Residues of mercury containing compounds are generally classified as “Special” waste. Contact your local waste disposal authority for advice ar an approved chemical disposal company.

13.3 **Multi Dose Vaccines Vials U.S.** - According to U.S. state and federal hazardous waste management requirements, discarded Thimerosal-preserved vaccines need to be managed as hazardous waste, using the waste code D009 (mercury).

## 14. Transport information

| | U. S. DOT (Domestic Surface Transportation) | IMO / IMDG (Ocean Transportation) | ICAO/IATA |
|---|---|---|---|
| **14.1. UN number** | Not Applicable | Not Regulated | Not Regulated |
| **14.2. UN proper shipping name** | Not Regulated | Not Regulated | Not Regulated |
| **14.3. Transport hazard class(es)** | **U.S. DOT Hazard Class:** D009 Mercury Waste – **for Multi Dose Vaccines Vials Only** According to U.S. state and federal hazardous waste management requirements, discarded Thimerosal-preserved vaccines shall be managed as hazardous waste, using the waste code D009 (mercury). | **IMDG:** Not Applicable **Sub Class:** Not Applicable | **Air Class:** Not Applicable |
| **14.4. Packing group** | Not Applicable | Not Applicable | Not Applicable |

**14.5. Environmental hazards**

**IMDG** Marine Pollutant: No

**14.6. Special precautions for user**

No further information

## 15. Regulatory information

**Regulatory U.S.** The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

**Toxic Substance Control Act ( TSCA)** All components of this material are either listed or exempt from listing on the TSCA Inventory.

**WHMIS Classification** Not Regulated

**US EPA Tier II Hazards**

**Fire:** No
**Sudden Release of Pressure:** No
**Reactive:** No
**Immediate (Acute):** No
**Delayed (Chronic):** No

**EPCRA 311/312 Chemicals and RQs:**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 302 Extremely Hazardous:**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 313 Toxic Chemicals:**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Carcinogens (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Developmental Toxins (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Female Repro Toxins (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Male Repro Toxins (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**N.J. RTK Substances (>1%) :**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Penn RTK Substances (>1%) :**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

## 16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

**The full text of the phrases appearing in section 3 is:**

Not Applicable

**This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.**

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