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
Gaskill Road, Speke
Liverpool L24 9GR
United Kingdom

Emergency
24 hour Emergency Telephone No.: 0151 705 5000
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]:

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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. 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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>None under normal conditions</td>
</tr>
<tr>
<td>Eyes</td>
<td>Protective safety glasses recommended</td>
</tr>
<tr>
<td>Skin</td>
<td>Protective gloves recommended.</td>
</tr>
<tr>
<td>Engineering Controls</td>
<td>None under normal conditions</td>
</tr>
<tr>
<td>Other Work Practices</td>
<td>Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.</td>
</tr>
</tbody>
</table>

9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>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.</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>pH</td>
<td>6.9 - 7.4</td>
</tr>
<tr>
<td>Melting point / freezing point</td>
<td>Not Determined</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not Determined</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Evaporation rate (Ether = 1)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Upper/lower flammability limits:</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Vapor pressure (Pa)</td>
<td>Not Determined</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>Not Determined</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not Determined</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water (Log Kow)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Viscosity (cSt)</td>
<td>Not Measured</td>
</tr>
</tbody>
</table>

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).

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Hazard Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
Adjuvanted Inactivated Influenza Vaccine

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
**Adjuvanted Inactivated Influenza Vaccine**

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**U. S. DOT (Domestic Surface Transportation)**

14.1. UN number
Not Applicable

14.2. UN proper shipping name
Not Applicable

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).

**IMO / IMDG (Ocean Transportation)**

Not Regulated

**ICAO/IATA**

Not Regulated

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**14.4. Packing group**
Not Applicable

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**14.5. Environmental hazards**

**IMDG**
Marine Pollutant: No

**14.6. Special precautions for user**
No further information

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**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

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire</td>
<td>No</td>
</tr>
<tr>
<td>Sudden Release of Pressure</td>
<td>No</td>
</tr>
<tr>
<td>Reactive</td>
<td>No</td>
</tr>
<tr>
<td>Immediate (Acute)</td>
<td>No</td>
</tr>
<tr>
<td>Delayed (Chronic)</td>
<td>No</td>
</tr>
</tbody>
</table>

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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