

Inactivated Influenza Vaccine

SDS Revision Date: 21 March 2017

1. Identification

1.1. Product identifier

Product Identity

Inactivated Influenza Vaccine (surface antigen)

Alternate Names

All egg-based 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

Calcium Chloride (10043-52-4), Trace

Neomycin, Trace

Polymyxin, Trace

Water for injection, up to 100%

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:

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.

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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 2C and 8C.

Incompatible materials: No data available.

7.3. Specific end use(s)

No data available.

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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 clear to slightly opaque liquid 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.

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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

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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 or 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

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	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.

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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.

The information contained herein is based upon data considered true and accurate. Seqirus makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

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