

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product name : Adjuvanted Influenza Vaccine  
Product code : Not available

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

Use of the substance/mixture : Inactivated Influenza Vaccine (Surface Antigen), suspension for injection

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

Seqirus  
475 Green Oaks Parkway  
Holly Springs, North Carolina 27540  
T +1-919-577-5000 (8AM-5PM)  
[www.seqirus.com](http://www.seqirus.com)

### 1.4. Emergency telephone number

Emergency number : US/Canada/Puerto Rico: 1-800-424-9300 (24 hrs); Outside North America: +1-703-527-3887 (24 hrs)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### GHS-US classification

Not classified.

### 2.2. Label elements

#### GHS-US labelling

No labelling applicable. This product is exempt from labeling as per OSHA 1910.1200(b)(5)(iii) - Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture.

### 2.3. Other hazards

No additional information available

### 2.4. Unknown acute toxicity (GHS US)

Not applicable

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product identifier	%
Influenza virus surface antigen (Haemagglutinin / Neuraminidase)	(CAS No) 92000-76-5 / 9001-67-6	0.0015*
MF-59 Adjuvant	(CAS No) 172889-84-8	50.00
Phosphate Buffered Saline and Stabilizing Solution	Various	Balance

\* The exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation : Not a normal route of exposure.  
First-aid measures after skin contact : In case of contact, immediately flush skin with plenty of water. Call a physician if irritation develops and persists.  
First-aid measures after eye contact : In case of contact, immediately flush eyes with plenty of water. Remove contact lenses, if worn. If irritation persists, get medical attention.

First-aid measures after ingestion

: Not a normal route of exposure. If swallowed, do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

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

Symptoms/injuries after inhalation	: Not a normal route of exposure.
Symptoms/injuries after skin contact	: May cause skin irritation. Symptoms may include redness, drying, defatting and cracking of the skin.
Symptoms/injuries after eye contact	: May cause eye irritation. Symptoms may include discomfort or pain, excess blinking and tear production, with possible redness and swelling.
Symptoms/injuries after ingestion	: May be harmful if swallowed. May cause stomach distress, nausea or vomiting.

### 4.3. Indication of any immediate medical attention and special treatment needed

Symptoms may not appear immediately. In case of accident or if you feel unwell, seek medical advice immediately (show the label or SDS where possible).

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Water spray, carbon dioxide, chemical powder, alcohol-resistant foam, halons.
Unsuitable extinguishing media	: None known.

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

Fire hazard	: Products of combustion may include, and are not limited to: oxides of carbon and oxides of nitrogen.
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### 5.3. Advice for firefighters

Protection during firefighting	: Keep upwind of fire. Wear full fire fighting turn-out gear (full Bunker gear) and respiratory protection (SCBA).
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## SECTION 6: Accidental release measures

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

General measures	: Restrict access to the area. Ensure clean-up is conducted by trained personnel only. Wear adequate protective clothing and equipment. Clean-up personnel need protection against contact with skin and eyes, as well as against inhalation.
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### 6.2. Methods and material for containment and cleaning up

For containment	: Contain spill, then place in a suitable container. <b>Do not flush to sewer or allow to enter waterways.</b> Use appropriate Personal Protective Equipment (PPE).
Methods for cleaning up	: Scoop up material and place in a disposal container. Wash contaminated surfaces with water and detergent, and collect washings for safe disposal. Provide ventilation.

### 6.3. Reference to other sections

See section 8 for further information on protective clothing and equipment and section 13 for advice on waste disposal.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling	: Avoid contact with skin and eyes. Do not swallow. Handle and open container with care. When using do not eat, drink or smoke. Dispose of contaminated materials in accordance with current regulations.
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### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep container tightly closed. Do not freeze. Protect from light.
Storage temperature	: 36 - 46 °C F

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

L-Alanine, L-tyrosyl-L-prolyl-L-tyrosyl-L-.alpha.-aspartyl-L-valyl-L-prolyl-L-.alpha.-aspartyl-L-tyrosyl- (92000-76-5)	
ACGIH	Not applicable
OSHA	Not applicable

Neuraminidase (9001-67-6)	
ACGIH	Not applicable
OSHA	Not applicable

### 8.2. Exposure controls

Appropriate engineering controls	: Use ventilation adequate to keep exposures (airborne levels of dust, fume, vapor, etc.) below recommended exposure limits.
Personal protective equipment	: Avoid all unnecessary exposure.
Hand protection	: Wear suitable waterproof gloves. Triple-gloves (rubber gloves and nitrile gloves, over latex gloves).
Eye protection	: Safety glasses or goggles are recommended when using product.
Skin and body protection	: None necessary under normal conditions of use.
Respiratory protection	: Not normally needed. In case of insufficient ventilation, wear suitable respiratory equipment.
Environmental exposure controls	: Maintain levels below Community environmental protection thresholds.
Other information	: Do not eat, smoke or drink where material is handled, processed or stored. Wash hands carefully before eating or smoking. Handle according to established industrial hygiene and safety practices.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state	: Liquid
Appearance	: Milky White Emulsion
Color	: Milky White
Odor	: Odorless
Odor threshold	: No data available
pH	: 6.9 – 7.7
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: Not flammable
Explosive limits	: No data available
Explosive properties	: Non explosive.
Oxidising properties	: Non oxidizing.
Vapour pressure	: No data available
Relative density	: $\approx 1$
Relative vapour density at 20 °C	: No data available
Solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

**9.2. Other information**

No additional information available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No dangerous reaction known under conditions of normal use.

**10.2. Chemical stability**

Stable under normal storage conditions.

**10.3. Possibility of hazardous reactions**

No dangerous reaction known under conditions of normal use.

**10.4. Conditions to avoid**

Heat. Incompatible materials.

**10.5. Incompatible materials**

Water-Reactive materials.

**10.6. Hazardous decomposition products**

May include, and are not limited to: oxides of carbon, oxides of nitrogen.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects**

Acute toxicity : Not classified.

## Safety Data Sheet

according to the Hazard Communication Standard (CFR29 1910.1200) HazCom 2012

Skin corrosion/irritation	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Based on available data, the classification criteria are not met. Contact with this product may cause an allergic reaction in sensitive individuals.
Germ cell mutagenicity	: Based on available data, the classification criteria are not met
Carcinogenicity	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Based on available data, the classification criteria are not met
Aspiration hazard	: Based on available data, the classification criteria are not met
Symptoms/injuries after inhalation	: Not a normal route of exposure.
Symptoms/injuries after skin contact	: May cause skin irritation. Symptoms may include redness, drying, defatting and cracking of the skin.
Symptoms/injuries after eye contact	: May cause eye irritation. Symptoms may include discomfort or pain, excess blinking and tear production, with possible redness and swelling.
Symptoms/injuries after ingestion	: May be harmful if swallowed. May cause stomach distress, nausea or vomiting.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : No known effects from this product.

### 12.2. Persistence and degradability

#### Adjuvanted Influenza Vaccine

Persistence and degradability	Not established.
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### 12.3. Bioaccumulative potential

#### Adjuvanted Influenza Vaccine

Bioaccumulative potential	Not established.
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### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

Effect on the global warming : No known effects from this product.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : This material must be disposed of in accordance with all local, state, provincial, and federal regulations. The generation of waste should be avoided or minimized wherever possible. Do not flush down sewers.

## SECTION 14: Transport information

### Department of Transportation (DOT)

In accordance with DOT  
Not regulated for transport

### Additional information

Other information : No supplementary information available.

Special transport precautions : Do not handle until all safety precautions have been read and understood.

**SECTION 15: Regulatory information****15.1. US Federal regulations**

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory except for:

L-Alanine, L-tyrosyl-L-prolyl-L-tyrosyl-L-.alpha.-aspartyl-L-valyl-L-prolyl-L-.alpha.-aspartyl-L-tyrosyl-	CAS No 92000-76-5
Phosphoric acid, disodium salt, dihydrate	CAS No 10028-24-7

**Neuraminidase (9001-67-6)**

EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C))
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**15.2. US State regulations****Adjuvanted Influenza Vaccine**

State or local regulations	No known effects from this product.
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**SECTION 16: Other information**

Date of issue	: 08/31/2016
Revision date	: 07/15/2020
Other information	: None.

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