

## 1. Identification

### Product identifier

**FLUARIX**

### Other means of identification

#### Synonyms

FLUARIX INJECTION 0.5 ML \* FLUARIX PRE-FILLED SYRINGE \* INFLUSPLIT SSW  
PRE-FILLED SYRINGE \* ALPHARIX \* INFLUENZA VIRUS VACCINE

### Recommended use

Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

### Recommended restrictions

No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

### Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
TRITON X 100	POLYOXYETHYLENE(10) OCTYLPHENYL ETHER	9002-93-1	1.25
MAGNESIUM CHLORIDE	MAGNESIUM DICHLORIDE * CHLOROMAGNESITE * MAGNESIUM CHLORIDE (MgCl <sub>2</sub> ) * Cl <sub>2</sub> Mg * OHS13360 * RTECS OM2800000 * GR44407X	7786-30-3	< 0.75
A/CHRISTCHURCH/16/2010 NIB-74XP (H1N1) (AN A/CALIFORNIA/7/2009-LIKE VIRUS)		Unassigned	0.22
A/VICTORIA/361/2011 IVR-165 (H3N2)		Unassigned	0.22
B/MASSACHUSETTS/2/2012 NYMC BX-51B		Unassigned	0.22
Other components below reportable levels			>98.0

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. First-aid measures

<b>Inhalation</b>	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.
<b>Skin contact</b>	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	Rinse mouth thoroughly. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
<b>Most important symptoms/effects, acute and delayed</b>	The following adverse effects have been noted with therapeutic use of this material: anorexia; irritability; drowsiness; headache; sweating; joint pain; fatigue; shivering.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
<b>General information</b>	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Move container from fire area if it can be done without risk.
<b>General fire hazards</b>	This product is expected to be non-combustible.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	<p>Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p> <p>Never return spills in original containers for re-use. For waste disposal, see section 13 of the SDS.</p> <p>Sodium hypochlorite (bleach) or other strong oxidizers can be used in clean-up decontamination operations. Contaminated surfaces should be washed with water, then bleach or other oxidizing solution, followed by another water wash.</p>
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	No special control measures required for the normal handling of this product. Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Store at 2 to 8 °C (36 to 46 °F). Do not freeze. Dispose of properly if frozen.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### GSK

#### Components

#### Type

#### Value

MAGNESIUM CHLORIDE  
(CAS 7786-30-3)

OHC

1

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

No particular ventilation requirements.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

#### Hand protection

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

#### Skin protection

##### Other

Wear suitable protective clothing.

#### Respiratory protection

No personal respiratory protective equipment normally required.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

#### Physical state

Liquid.

#### Form

Vaccine. Pre-filled syringe.

#### Color

Colorless. Clear, free of visible particles.

### Odor

Not available.

### Odor threshold

Not available.

### pH

Not available

### Melting point/freezing point

Not available.

### Initial boiling point and boiling range

Not available.

### Flash point

Not available

### Evaporation rate

Not available

### Flammability (solid, gas)

Not available.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

#### Explosive limit - lower (%)

Not available.

#### Explosive limit - upper (%)

Not available.

### Vapor pressure

Not available

### Vapor density

Not available

### Relative density

Not available.

### Solubility(ies)

#### Solubility (water)

Not available.

### Partition coefficient (n-octanol/water)

Not available.

### Auto-ignition temperature

Not available.

### Decomposition temperature

Not available.

Viscosity Not available

## 10. Stability and reactivity

**Reactivity** Not available.

**Chemical stability** Material is stable under normal conditions. DO NOT FREEZE - dispose of properly if frozen.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Contact with incompatible materials.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

**Ingestion** Expected to be a low ingestion hazard.

**Inhalation** Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin contact** Health injuries are not known or expected under normal use.

**Eye contact** Health injuries are not known or expected under normal use. Avoid contact with eyes.

**Symptoms related to the physical, chemical and toxicological characteristics** The following adverse effects have been noted with therapeutic use of this material: anorexia; irritability; drowsiness; headache; sweating; fatigue; joint pain; shivering.

### Information on toxicological effects

**Acute toxicity** Health injuries are not known or expected under normal use.

Components	Species	Test Results
------------	---------	--------------

MAGNESIUM CHLORIDE (CAS 7786-30-3)

#### Acute

##### Inhalation

NOAEL	Rabbit	> 3.9 mg/m3
-------	--------	-------------

##### Oral

LD50	Rat	2800 mg/kg
------	-----	------------

\* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use.

### Respiratory or skin sensitization

**Respiratory sensitization** None known.

**Skin sensitization** This product is not expected to cause skin sensitization.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** None known.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

**Reproductive toxicity** Contains no ingredient listed as toxic to reproduction

**Specific target organ toxicity - single exposure** None known.

**Specific target organ toxicity - repeated exposure** None known.

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** None known.

**Further information** Caution - Pharmaceutical agent.

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	Not available.

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

<b>DOT</b>	Not regulated as a dangerous good.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

### 15. Regulatory information

#### US federal regulations

##### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

##### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

##### SARA 304 Emergency release notification

Not regulated.

##### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
--------------------------	---

##### SARA 302 Extremely hazardous substance

Not listed.

<b>SARA 311/312 Hazardous chemical</b>	No
--	----

##### SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

##### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

##### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

#### US state regulations

##### US. Massachusetts RTK - Substance List

Not regulated.

##### US. New Jersey Worker and Community Right-to-Know Act

Not listed.

##### US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

##### US. Rhode Island RTK

Not regulated.

##### US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

**Issue date** 08-27-2014

**Revision date** 08-27-2014

**Version #** 21

**Further information** HMIS® is a registered trade and service mark of the NPCA.

**HMIS® ratings**  
Health: 1  
Flammability: 0  
Physical hazard: 0

**NFPA ratings**  
Health: 1  
Flammability: 0  
Instability: 0

**References** GSK Hazard Determination

**Disclaimer** The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**Revision Information**  
Composition / Information on Ingredients: Disclosure Overrides  
Toxicological information: Inhalation  
Disposal considerations: Disposal instructions  
Regulatory Information: United States  
Other information, including date of preparation or last revision: References  
Other information, including date of preparation or last revision: Further information