



SAFETY DATA SHEET

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 of the chemical and restrictions on use

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.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
TRITON X 100 POLYOXYETHYLENE(10) OCTYLPHENYL ETHER	9002-93-1	1.25
MAGNESIUM CHLORIDE MAGNESIUM DICHLORIDE CHLOROMAGNESITE Magnesium chloride (MgCl ₂) Cl ₂ 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

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. #: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

4. First-aid measures

Description of necessary first aid measures

Inhalation	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.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	Rinse mouth thoroughly. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Personal protection for first-aid responders	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.
Symptoms caused by exposure	The following adverse effects have been noted with therapeutic use of this material: anorexia; irritability; drowsiness; headache; sweating; joint pain; fatigue; shivering.
Medical attention and special treatment	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.

Hazchem Code Not available.

General fire hazards This product is expected to be non-combustible.

Specific methods Move container from fire area if it can be done without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	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.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

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.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills in original containers for re-use. For waste disposal, see section 13.

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.

Clean up in accordance with all applicable regulations.

Other issues relating to spills and releases

7. Handling and storage

Precautions for safe handling

No special control measures required for the normal handling of this product. Avoid prolonged exposure. Observe good industrial hygiene practices. Use care in handling/storage. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

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 and personal protection

Control parameters

Follow standard monitoring procedures.

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).

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

No particular ventilation requirements.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection

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

Skin protection

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.

Other

Wear suitable protective clothing.

Respiratory protection

No personal respiratory protective equipment normally required.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

Hygiene measures

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.

Colour

Colorless. Clear, free of visible particles.

Odour

Not available.

Odour 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.
Vapour pressure	Not available
Vapour 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. None under normal conditions.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on possible 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 exposure	The following adverse effects have been noted with therapeutic use of this material: anorexia; irritability; drowsiness; headache; sweating; fatigue; joint pain; shivering.

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test results
MAGNESIUM CHLORIDE (CAS 7786-30-3)		
Acute		
<i>Inhalation</i>		
NOAEL	Rabbit	> 3.9 mg/m3
<i>Oral</i>		
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/irritation	Health injuries are not known or expected under normal use.

Respiratory or skin sensitisation

Respiratory sensitisation	None known.
Skin sensitisation	This product is not expected to cause skin sensitisation.
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.
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.
Other information	Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity	Not expected to be harmful to aquatic organisms.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal methods	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.
Residual waste	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).
Contaminated packaging	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

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

Safety, health and environmental regulations

National regulations	This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)
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Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

Australia National Pollutant Inventory (NPI): Threshold quantity

MAGNESIUM CHLORIDE (CAS 7786-30-3)

10 TONNES/YR Threshold Category: 1

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. The product does not need to be labelled in accordance with EC directives or respective national laws.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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

Issue date	27-August-2014
Revision date	27-August-2014
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	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: TRANSPORT INFORMATION: Regulatory Information: United States GHS: Classification