



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** VARILRIX

**Other means of identification**

**Synonyms**

VACUNA ANTIVARICELLA \* VARILRIX, VARICELLA VIRUS VACCINE (LIVE ATTENUATED) \* VACCINE, VARILRIX (VARICELLA VIRUS) \* VARILRIX AMPOLLA \* VARILRIX DURCHSTICHLASCHE MIT LOSUNGSMITTEL \* VARILRIX ENJEKSIYON \* VARILRIX FERTIGSPRITZE \* VARILRIX FLACON MONODOSE \* VARILRIX FLACONE \* VARILRIX FRASCO AMPOLLA \* VARILRIX FRASCO AMPOLLA + JERINGA PRELENADA \* VARILRIX FRASCO AMPOLLA LIOFILIZADA \* VARILRIX INJECTABLE \* VARILRIX INJECTION \* VARILRIX INJEKTIOKUVA-AINE JA LIUOTIN \* VARILRIX INJEKTIONSVATSKA \* VARILRIX INJETAVEL \* VARILRIX JERINGA PRELENA \* VARILRIX LIOFILIZAT \* VARILRIX LYOPHILIZED POWDER VIAL \* VARILRIX LYOPHILIZED VACCINE \* VARILRIX PEDIATRICO \* VARILRIX PRELENADA \* VARILRIX PULVER OG VAESKE TIL INJEKSJONVAESKE \* VARILRIX PULVERIS INJEKCIJAM \* VARILRIX SERINGA PREUMPLUTA \* VARILRIX SERINGUE PREREMPLIE \* VARILRIX VACCINE INJECTION \* VARILRIX VIAL

**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

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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
LIVE ATTENUATED VARICELLA VIRUS (OKA STRAIN)	Unassigned	<1
Other components below reportable levels		>99

## 4. First-aid measures

### Description of necessary first aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.
<b>Personal protection for first-aid responders</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
<b>Symptoms caused by exposure</b>	None known.
<b>Medical attention and special treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

## 5. Fire-fighting measures

### Extinguishing media

<b>Suitable extinguishing media</b>	Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). Water.
<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 fire fighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Hazchem Code</b>	Not available.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	Keep unnecessary personnel away. For personal protection, see section 8.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

## 7. Handling and storage

### Precautions for safe handling

<b>Conditions for safe storage, including any incompatibilities</b>	Observe good industrial hygiene practices.
	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls and personal protection

### Control parameters

### Occupational exposure limits

**GSK**

Not established

### Biological limit values

### Exposure guidelines

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

<b>Appropriate engineering controls</b>	General ventilation normally adequate.
<b>Individual protection measures, for example personal protective equipment (PPE)</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
<b>Other</b>	Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>Hygiene measures</b>	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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Lyophilised powder.Vial.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit – upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.

<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on possible routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Symptoms related to exposure</b>	None known.
<b>Acute toxicity</b>	Health injuries are not known or expected under normal use.
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/irritation</b>	None known. Health injuries are not known or expected under normal use.
<b>Respiratory or skin sensitisation</b>	
<b>Respiratory sensitisation</b>	Due to partial or complete lack of data the classification is not possible.
<b>Skin sensitisation</b>	None known. This product is not expected to cause skin sensitisation.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Carcinogenicity</b>	Carcinogenic effects are not expected as a result of occupational exposure.
<b>Reproductive toxicity</b>	Contains no ingredient listed as toxic to reproduction
<b>Specific target organ toxicity - single exposure</b>	None known.
<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not likely, due to the form of the product.
<b>Other information</b>	Occupational exposure to the substance or mixture may cause adverse effects.

## 12. Ecological information

<b>Ecotoxicity</b>	Not expected to be harmful to aquatic organisms.
<b>Persistence and degradability</b>	Not available.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available for this product.
<b>Mobility in general</b>	Not available.
<b>Other adverse effects</b>	Not available.

## 13. Disposal considerations

<b>Disposal methods</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>Residual waste</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). Avoid discharge into water courses or onto the ground.
<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

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

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

## 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.)

#### **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.

#### **High Volume Industrial Chemicals (HVIC)**

Not listed.

#### **Importation of Ozone Deleting 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**

**Stockholm Convention**

Not applicable.

**Rotterdam Convention**

Not applicable.

**Kyoto protocol**

Not applicable.

**Montreal Protocol**

Not applicable.

**Basel Convention**

Not applicable.

**International Inventories**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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**

<b>Issue date</b>	17-October-2014
<b>Revision date</b>	17-October-2014
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision Information</b>	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Toxicological Information: Reproductive Toxicology Regulatory Information: United States GHS: Classification