

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 DURCHSTICHFLASCHE MIT LOSUNGSMITTEL * VARILRIX ENJEKSIYON * VARILRIX FERTIGSPRITZE * VARILRIX FLACON MONODOSE * VARILRIX FLACONE * VARILRIX FRASCO AMPOLLA * VARILRIX FRASCO AMPOLLA + JERINGA PRELLENADA * VARILRIX FRASCO AMPOLLA LIOFILIZADA * VARILRIX INJECTABLE * VARILRIX INJECTION * VARILRIX INJEKTIOKUIVA-AINE JA LIUOTIN * VARILRIX INJEKTIONSVATSKA * VARILRIX INJETAVEL * VARILRIX JERINGA PRELLENA * VARILRIX LIOFILIZAT * VARILRIX LYOPHILIZED POWDER VIAL * VARILRIX LYOPHILIZED VACCINE * VARILRIX PEDIATRICO * VARILRIX PRELLENADA * VARILRIX PULVER OG VAESKE TIL INJEKJONSVAESKE * VARILRIX PULVERIS INJEKCIJAM * VARILRIX SERINGA PREUMPLUTA * VARILRIX SERINGUE PREREMPLIE * VARILRIX VACCINE INJECTION * VARILRIX VIAL

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
Website: 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	%
MANNITOL	D-MANNITOL * 1,2,3,4,5,6-HEXANEHEXOL * MANNA SUGAR * MANNITE * OSMITROL * BP-686 * MANNITOL, D- * DIOSMOL * MANITON-S * MANNIDEX * MANNIGEN * MANNISTOL * OSMOSOL * D-MANNITE * CORDYCEPIC ACID * D-(-)-MANNITOL * MANNITOLUM * OSMOSAL * ISOTOL * C6H14O6 * OHS13660 * RTECS OP2060000	69-65-8	15
D-SORBITOL	SORBITOL * L-GULITOL * 1,2,3,4,5,6-HEXANEHEXOL * D-SORBOL	50-70-4	11
LIVE ATTENUATED VARICELLA VIRUS (OKA STRAIN)		Unassigned	<1
Other components below reportable levels			>99

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

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	None known.
Indication of immediate medical attention and special treatment needed	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	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.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO2). Water.
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 firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	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.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Type

Value

D-SORBITOL (CAS
50-70-4)

OHC

1

MANNITOL (CAS 69-65-8)

OHC

1

Biological limit values

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

Exposure guidelines

Appropriate engineering controls

General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

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

Skin protection

Hand protection

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other

Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state

Solid.

Form

Lyophilised powder.Vial.

Color

Not available.

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	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
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	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

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.
Ingestion	Health injuries are not known or expected under normal use. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics None known.

Information on toxicological effects

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

Components	Species	Test Results
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D-SORBITOL (CAS 50-70-4)

Acute

Oral

LD50

Rat

15.9 g/kg

MANNITOL (CAS 69-65-8)

Acute

Oral

LD50

Rat

13.5 g/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 Due to partial or complete lack of data the classification is not possible.

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 Carcinogenic effects are not expected as a result of occupational exposure.

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 likely, due to the form of the product.

Further information Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Persistence and degradability Not available.

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

D-SORBITOL -2.2

MANNITOL -3.1

Bioconcentration factor (BCF)

D-SORBITOL 1 Estimated

MANNITOL 1 Estimated

Mobility in soil Not available.

Adsorption

Soil/sediment sorption - log Koc

D-SORBITOL 0.3 Estimated

MANNITOL 0.7 Estimated

Mobility in general Not available.

Volatility

Henry's law

D-SORBITOL 0 atm m³/mol Estimated

MANNITOL 0 atm m³/mol

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products 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.

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

DOT

Not regulated as a dangerous good.

Not available.

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 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.

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Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 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	This document has undergone significant changes and should be reviewed in its entirety.