



SAFETY DATA SHEET

1. Identification

Product identifier	TRIVALENT INFLUENZA VACCINE (WITHOUT THIMEROSAL)
Other means of identification	
Synonyms	FLULAVAL (Q-TIV TF) TRIVALENT THIMEROSAL-FREE VACCINE * FLULAVAL (INFLUENZA VIRUS VACCINE) INTRAMUSCULAR INJECTION * FLULAVAL WITHOUT THIMEROSAL * INFLUENZA VIRUS VACCINE, TRIVALENT, INACTIVATED * VACCINE, FORMULATED PRODUCT
Recommended use	Medicinal Product. This safety data sheet (SDS) has been prepared in accordance with workplace safety standards which require identification of all known hazards of the material regardless of potential risk. The information is intended for people handling the material in the workplace. Warnings included may not apply in all cases. Needs may vary depending upon the potential for exposure in the workplace. The SDS is not intended to provide information relevant to final use of the material for the purpose intended. Consumers/Patients should consult prescribing information/package insert/product label or consult their chemist or physician.
Recommended restrictions	No other uses are advised.
Manufacturer/Importer/Supplier/Distributor information	

COMPANY NAME	GSK
Address:	410 Blackwell Street Durham, NC, 27701
Telephone:	+1-888-825-5249 (GSK General Inquiries) +1-877-844-8872 (ViiV General Inquiries)
Email:	msds@gsk.com
Website:	www.gsk.com

EMERGENCY CONTACTS

Telephone:	3E GLOBAL INCIDENT RESPONSE +(1) 760 476 3971 (In country) +(1) 760 476 3962 or +(1) 866 519 4752 (International) 24/7; multi-language response
Contract Number:	334878

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.

Hazard(s) not otherwise classified (HNOC) Caution - Pharmaceutical agent.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
SODIUM CHLORIDE	COMMON SALT ROCK SALT SODIUM MONOCHLORIDE SALT SEA SALT TABLE SALT SALT, WHITE CRYSTALS, SOLAR	7647-14-5	0.85
POLYSORBATE 80	POLYETHYLENE OXIDE SORBITAN MONO-OLEATE POLYOXYETHYLENE SORBITAN MONOOLEATE POLYOXYETHYLENE (20) SORBITAN MONO-OLEATE POLYOXYETHYLENE SORBITAN OLEATE POLYSORBATE 80, U.S.P. SORBIMACROGOL OLEATE TWEEN 80 TWEEN 81 TWEEN 80 A POLYOXYETHYLENE SORBITAN MONOOLEATE (POLYSORBATE 80)	9005-65-6	0.102
POTASSIUM CHLORIDE	POTASSIUM CHLORIDE (KCL) POTASSIUM MONOCHLORIDE SUPER K (SALT) POTASSIUM MURIATE	7447-40-7	0.02
POTASSIUM PHOSPHATE MONOBASIC	POTASSIUM ACID PHOSPHATE POTASSIUM DIPHOSPHATE POTASSIUM BIPHOSPHATE POTASSIUM ORTHOPHOSPHATE MONOPOTASSIUM PHOSPHATE POTASSIUM DIHYDROGEN PHOSPHAT E POTASSIUM DIHYDROGEN ORTHOPHOSPHATE POTASSIUM PHOSPHATE, MONOBASIC	7778-77-0	0.02
INACTIVATED FLU VIRUS		Unassigned	0.009
Other components below reportable levels			> 90

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: muscle pain. Headache. Fatigue.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Carbon dioxide (CO2). Dry chemical powder.
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	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. 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 to original containers for re-use. 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 tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK Components	Type	Value	Form
POLYSORBATE 80 (CAS 9005-65-6)	OHC	1	>1000 - <=5000 mcg/m3 PROVISIONAL
POTASSIUM CHLORIDE (CAS 7447-40-7)	OHC	1	>1000 - <=5000 mcg/m3
POTASSIUM PHOSPHATE MONOBASIC (CAS 7778-77-0)	OHC	1	>1000 - <=5000 mcg/m3
SODIUM CHLORIDE (CAS 7647-14-5)	OHC	1	

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Exposure guidelines

Appropriate engineering controls	General ventilation normally adequate.
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Individual protection measures, such as personal protective equipment

Eye/face protection	Not normally needed. 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	Not normally needed. 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.
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9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Pre-filled syringe or Vial
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	7.1
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 applicable.

Upper/lower flammability or explosive limits

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
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Health injuries are not expected as a result of occupational exposure or intended use.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not expected as a result of occupational exposure or intended use.
Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: muscle pain. Fatigue. Headache.

Information on toxicological effects

Acute toxicity	Health injuries are not expected as a result of occupational exposure or intended use.
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Components	Species	Test Results
POTASSIUM CHLORIDE (CAS 7447-40-7)		
<u>Acute</u>		
Oral		
LD50	Rat	2600 mg/kg
POTASSIUM PHOSPHATE MONOBASIC (CAS 7778-77-0)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 300 mg/kg, 24 Hours
Oral		
LD50	Mouse	1700 mg/kg
SODIUM CHLORIDE (CAS 7647-14-5)		
<u>Acute</u>		
Oral		
LD50	Rat	3000 mg/kg
Skin corrosion/irritation	No adverse effects due to skin contact are expected.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitization	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.	
Respiratory sensitization	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.	
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	No data available to indicate product or any components present at greater than 0.1% are carcinogenic. Carcinogenic effects are not expected as a result of occupational exposure.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.	
Specific target organ toxicity - single exposure	Not assigned. Based on available data, the classification criteria are not met.	
Specific target organ toxicity - repeated exposure	Not assigned. Based on available data, the classification criteria are not met.	
Aspiration hazard	Not an aspiration hazard.	
Chronic effects	Prolonged inhalation may be harmful.	
Further information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.	

12. Ecological information

Ecotoxicity No data available for this product. Not expected to be harmful to aquatic organisms.

Components	Species	Test Results
POTASSIUM CHLORIDE (CAS 7447-40-7)		
Aquatic		
<i>Acute</i>		
Algae	NOEC	Green algae (Chlorella vulgaris) 600 mg/l, 4 months
Crustacea	EC50	Water flea (Daphnia magna) 83 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus) 951 mg/l, 96 hours Static test
		Channel catfish (Adult Ictalurus punctatus) 720 mg/l, 48 hours Static test

Components		Species	Test Results
		Fathead minnow (Adult Pimephales promelas)	880 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	435 mg/l, 96 hours Static test
SODIUM CHLORIDE (CAS 7647-14-5)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Algae (Nitscheria linearis)	2430 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	3310 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	1295 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas)	6390 mg/l, 96 hours Static test
		Goldfish (Adult Carassius auratus)	7000 mg/l, 96 hours
		Mosquito fish (Adult Gambusia affinis)	17550 mg/l, 96 hours Static test
Persistence and degradability		No data is available on the degradability of any ingredients in the mixture.	
Bioaccumulative potential		Not available.	
Mobility in soil		No data available.	
Mobility in general		Not available.	
Other adverse effects		Not available.	

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
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).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT	Not regulated as a dangerous good.
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 applicable.

15. Regulatory information

US federal regulations	This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
Toxic Substances Control Act (TSCA)	
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 1910.1001-1053)	
Not listed.	

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

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

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. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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	09-06-2018
Revision date	05-16-2024
Version #	07
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	This document has undergone significant changes and should be reviewed in its entirety.