



SAFETY DATA SHEET

1. Identification

Product identifier FLULAVAL
Other means of identification Not available.
Synonym(s) FLULAVAL (INFLUENZA VIRUS VACCINE) INTRAMUSCULAR INJECTION * VACCIN FLUVIRAL * GRIPLAVAL * INFLUENZA VIRUS VACCINE, TRIVALENT, INACTIVATED
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

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT	MERCURATE(1-), ETHYL(2-MERCAPTOBENZOATE(2-)-O,S)-, SODIUM MERCURY, ETHYL(HYDROGEN O-MERCAPTOBENZOATO)-, SODIUM SALT ETHYL(2-MERCAPTOBENZOATO(2-)-O,S)-I SODIUM ((O-CARBOXYPHENYL)THIO)ETHYLMERCI SODIUM SALT ETHYLMERCURITHIOSALICYLIC ACID, SODIUM SALT ETHYL(HYDROGEN O-MERCAPTOBENZOATO)MERCURY SODIUM SALT ETHYL (SODIUM-O-MERCAPTOBENZOATE)MERC SODIUM ETHYLMERCURITHIOSALICYLATI MERCUROTHIOLATE MERTHIOLATE SODIUM MERTHIOLATE SET THIMEROSAL C9H9HGNAO2S OHS09625 RTECS OV8400000	54-64-8	0.01
INACTIVATED MONOVALENT SPLIT-VIRION DRUG SUBSTANCE, A/H1N1			0.002
INACTIVATED MONOVALENT SPLIT-VIRION DRUG SUBSTANCE, A/H3N2			0.002
INACTIVATED MONOVALENT SPLIT-VIRION DRUG SUBSTANCE, B STRAIN			0.002
Other components below reportable levels			>99.0

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

4. 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 center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: anorexia; irritability; drowsiness; headache; sweating; joint pain; fatigue; shivering; sore throat; coughing; malaise.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
General information	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

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
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 Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.

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 Keep unnecessary personnel away. Wear protective clothing and equipment consistent with the degree of hazard. For personal protection, see section 8 of the MSDS.

Methods and materials for containment and cleaning up Collect and place it in a suitable, properly labelled container for recovery or disposal.

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. 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 of the MSDS. Water can be used for clean-up and decontamination operations. 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.

Environmental precautions For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

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.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS). 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
Not established

US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
ETHYLMERCURITHIOSALI CYLIC ACID SODIUM SALT (CAS 54-64-8)	Ceiling	0.04 mg/m3
	TWA	0.01 mg/m3

US. ACGIH Threshold Limit Values

Components	Type	Value
ETHYLMERCURITHIOSALI CYLIC ACID SODIUM SALT (CAS 54-64-8)	STEL	0.03 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
ETHYLMERCURITHIOSALI CYLIC ACID SODIUM SALT (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
ETHYLMERCURITHIOSALI CYLIC ACID SODIUM SALT (CAS 54-64-8)	35 µg/g	Total inorganic mercury	Creatinine in urine	*
	15 micrograms/liter	Total inorganic mercury	Blood	*

* - For sampling details, please see the source document.

Exposure guidelines

US - Tennessee OELs: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Can be absorbed through the skin.
(CAS 54-64-8)

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Can be absorbed through the skin.
(CAS 54-64-8)

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.

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. Vial.

Color Colorless. Clear, free of visible particles.

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 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) 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. 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	None known.
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; sore throat; coughing; malaise.

Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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 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.
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.
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 instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Observe all local and national regulations when disposing of this product. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
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	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.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

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.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
 Immediate Hazard - No
 Delayed Hazard - No
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

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

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

DEA Essential Chemical Code Number

Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations**US. Massachusetts RTK - Substance List**

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

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

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT 500 lbs
 (CAS 54-64-8)

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

US. Rhode Island RTK

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Listed: July 1, 1990
 (CAS 54-64-8)

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

Country(s) or region	Inventory name	On inventory (yes/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 this product complies 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	07-09-2013
Revision date	07-09-2013
Version #	10
Further information	This material has not been assessed for HMIS or NFPA ratings. HMIS® is a registered trade and service mark of the NPCA.
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: Ingredients Physical & Chemical Properties: Multiple Properties Regulatory Information: United States