

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Fluzone® Quadrivalent, Influenza Vaccine

Other means of identification

Product Information Single-dose vial in package of 10 vials
Single-dose, prefilled syringe, without needle 0.5 mL in package of 10
Multi-dose vial in package of one

Synonyms Quadrivalent Influenza Vaccine

Recommended use of the chemical and restrictions on use

Recommended Use Active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.
Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address
Sanofi Pasteur
1 Discovery Drive
Swiftwater, PA 18370
Phone: 1-800-822-2463 (1-800-VACCINE)

Emergency telephone number

24 Hour Emergency Phone 1-703-741-5970 / 1-800-424-9300 CCN # 2118 (CHEMTREC)

2. HAZARDS IDENTIFICATION

Classification

Health Hazards
Not classified.

Physical hazards
Not classified.

OSHA Regulatory Status
This product is a vaccine that is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows throughout the sheet.

Label elements

Emergency Overview

Normal precautions common to safe manufacturing practice should be followed in handling and storage.

Appearance Clear and slightly opalescent suspension	Physical state Liquid	Odor Not available.
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Hazards not otherwise classified (HNOC)
Not classified as a hazardous substance.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Fluzone Quadrivalent

Chemical Name	CAS No.	Weight-%
Split Influenza Virus, inactivated strains	N/A	0.012
Sodium phosphate-buffered isotonic sodium chloride solution	N/A	q.s. to 100
Thimerosal 50µg/0.5 mL(per dose)*	54-64-8	0.01

Note: Ingredients below reportable levels are not listed.

*Note: Only the multi-dose vial contains Thimerosal, a mercury derivative.

4. FIRST AID MEASURES

First aid measures

Eye contact

In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact

In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation

In case of inhalation, remove to fresh air. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion

In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention if needed. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-protection of the first aider

Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms

Common effects of the vaccine include the following: pain, tenderness, erythema, and swelling of the injection site; swelling; irritability; abnormal crying; malaise; drowsiness; appetite loss; myalgia; vomiting; fever; headache.

Indication of any immediate medical attention and special treatment needed

Note to physicians

Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical

Not available.

Hazardous combustion products Not available.

Explosion data

Sensitivity to Mechanical Impact Not available.

Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Wear appropriate personal protective equipment (see Section 8).

Environmental precautions

Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up

Wipe up with absorbent material (e.g. cloth) for disposal. Area where spill occurred can be cleaned with the regular cleaning materials designated for the area.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store at 2° to 8°C (35° to 46°F). Do not freeze.

Incompatible materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Controls Used as supplied, no special engineering controls are needed when administering the vaccine.

Individual protection measures, such as personal protective equipment

Eye/face protection In laboratory or industrial settings, safety glasses with side shields are recommended

Skin and body protection In laboratory or industrial settings, gloves and lab coats are recommended.

Respiratory protection Used as supplied, general room ventilation is acceptable and no special respiratory protection is needed when administering the vaccine.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid	Odor	Not available.
Appearance	Clear and slightly opalescent suspension	Odor threshold	Not available.
Color	Clear to slightly opalescent		

Property

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	Not available.	
Melting point/freezing point	Not available.	

Boiling point / boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Flammability Limit in Air	
Upper flammability limit:	Not available.
Lower flammability limit:	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Specific Gravity	Not available.
Water solubility	Not available.
Solubility in other solvents	Not available.
Partition coefficient	Not available.
Autoignition temperature	Not available.
Decomposition temperature	Not available.
Kinematic viscosity	Not available.
Dynamic viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
<u>Other Information</u>	
Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal handling.

Hazardous polymerization	Hazardous polymerization does not occur.
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Conditions to avoid

Not available.

Incompatible materials

Not available.

Hazardous Decomposition Products

None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	No data available.
Inhalation	No impact known or expected under normal use.
Eye contact	No impact known or expected under normal use.
Skin Contact	No impact known or expected under normal use.

Ingestion No impact known or expected under normal use.

Information on toxicological effects

Symptoms

Common effects of the vaccine include the following: pain, tenderness, erythema, and swelling of the injection site; swelling; irritability; abnormal crying; malaise; drowsiness; appetite loss; myalgia; vomiting; fever; headache.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation

Not available.

Serious eye damage/eye irritation

Not available.

Irritation

Not available.

Corrosivity

Not available.

Sensitization

Not available.

Germ cell mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive toxicity

Available data with Fluzone Quadrivalent use in pregnant women are insufficient to inform vaccine-associated risk of adverse developmental outcomes. A developmental and reproductive toxicity study was performed in female rabbits given a 0.5 mL/dose of Fluzone Quadrivalent prior to mating and during gestation (a single human dose is 0.5 mL). This study revealed no adverse effects to the fetus or pre-weaning development due to Fluzone Quadrivalent. It is not known whether Fluzone Quadrivalent is excreted in human milk. Data are not available to assess the effects of Fluzone Quadrivalent on the breastfed infant or on milk production/excretion.

Developmental Toxicity

Not available.

Teratogenicity

Not available.

STOT - single exposure

Not classified.

STOT - repeated exposure

Not classified.

Chronic toxicity

Not available.

Subchronic toxicity

Not available.

Target Organ Effects

Not available.

Neurological effects

Not available.

Other adverse effects

Not available.

Aspiration hazard

Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Not available.

Persistence and degradability

Not available.

Bioaccumulation

Not available.

Mobility

Not available.

Other adverse effects

Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging

Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number

Not applicable.

California Hazardous Waste Codes Not applicable.

14. TRANSPORT INFORMATION

DOT Not regulated.
TDG Not regulated.
MEX Not regulated.
ICAO (air) Not regulated.
IATA Not regulated.
IMDG Not regulated.
RID Not regulated.
ADR Not regulated.
ADN Not regulated.

15. REGULATORY INFORMATION

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains the following chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical Name	CAS No.	Weight-%	SARA 313 – Threshold Values %
Thimerosal – 54-64-8	54-64-8	0.01	1.0

Note: Only the multi-dose vial contains thimerosal.

SARA 311/312 Hazard Categories

Acute health hazard No
 Chronic Health Hazard No
 Fire hazard No
 Sudden release of pressure hazard No
 Reactive Hazard No

CWA (Clean Water Act)

This product contains the following substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Chemical Name	CWA – Reportable Quantities	CWA – Toxic Pollutants	CWA – Priority Pollutants	CWA – Hazardous Substances
Thimerosal 54-64-8	-	X	-	-

Note: Only the multi-dose vial contains thimerosal.

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355).

US State Regulations**California Proposition 65**

Component (Thimerosal) is on proposition 65-list; however, based on percentage of formulation it is not considered hazardous.

Note: Only the multi-dose vial contains thimerosal.

Component (Formaldehyde) is on proposition 65-list; however, based on percentage of formulation it is not considered hazardous.

U.S. State Right-to-Know Regulations

This drug is regulated by the Food and Drug Administration and is therefore exempt from State Right-to-Know Regulations.

16. OTHER INFORMATION

Prepared By	IES Engineers
Issue Date	17-Apr-2015
Revision Date	04-Aug-2020
Revision Note	Updated Section 1: Product Information and Address. Revised by Sanofi Pasteur.

Disclaimer

Sanofi Pasteur considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. Sanofi Pasteur cannot be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet