## 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.

**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 | | |
| **Appearance** | Clear and slightly opalescent suspension | **Odor** | Not available. |
| **Color** | Clear to slightly opalescent | **Odor threshold** | Not available. |

| **Property** | **Values** | **Remarks • Method** |
|---|---|---|
| **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. |

**Other Information**

| | |
|---|---|
| **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.

**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** | 07-July-2021 |
| **Revision Note** | Updated Revision Date and Version. Revised by Sanofi Pasteur. |

**Disclaimer**

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**End of Safety Data Sheet**