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

Product identifier

Product Name  Fluzone® Intradermal Quadrivalent

Other means of identification

Product Information  Single dose prefilled microinjection system in package of 10

Synonyms  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

Emergency telephone number

Company Phone Number  1-800-VACCINE (1-800-822-2463)
24 Hour Emergency Phone Number  1-570-957-4400
Emergency Telephone  1-570-957-4400

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

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Physical state</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear and slightly</td>
<td>Liquid</td>
<td>Not available.</td>
</tr>
<tr>
<td>opalescent suspension</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Hazards not otherwise classified (HNOC)
Not classified as a hazardous substance.
3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms
Influenza Vaccine

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Split Influenza Virus, inactivated strains</td>
<td>N/A</td>
<td>0.036</td>
</tr>
<tr>
<td>Sodium phosphate-buffered isotonic sodium chloride solution</td>
<td>N/A</td>
<td>q.s. to 100</td>
</tr>
</tbody>
</table>

Note: Ingredients below reportable levels are not listed.

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, pruritus, erythema, swelling, and induration of the injection site; myalgia; headache; malaise; shivering.

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
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
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appearance</td>
<td>Clear and slightly opalescent suspension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>Slightly opalescent.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Odor</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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, pruritus, erythema, swelling, and induration of the injection site; myalgia; headache; malaise; shivering.

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
Pregnancy Category B: The developmental and reproductive toxicity study performed with the trivalent formulation of Fluzone Intradermal is relevant to Fluzone Intradermal Quadrivalent because both vaccines share the same manufacturing process and route of administration. The study, in which the trivalent formulation of Fluzone Intradermal (27 mcg) was administered to female rabbits at a dose approximately 20 times the human dose (on a mg/kg basis), revealed no evidence of impaired female fertility or harm to the fetus. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Fluzone Intradermal Quadrivalent should be used during pregnancy only if clearly needed.

It is not known whether Fluzone Intradermal Quadrivalent is excreted in human milk. Because many drugs are excreted in human milk, the decision to give Fluzone Intradermal Quadrivalent to a nursing woman should be based on careful consideration of the potential benefits and risks.

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 does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories
<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute health hazard</td>
<td>No</td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Fire hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden release of pressure hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

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
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations
This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information
EPA Pesticide Registration Number
Not applicable.
16. OTHER INFORMATION

Revision Date
Revision Note
Not available.

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