

**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING****Product identifier****Product Name** Flublok® Quadrivalent Influenza Vaccine**Other means of identification****Product Information** Single dose pre-filled syringe in package of 10 syringes.  
Solution of recombinant hemagglutinin (HA) proteins from four influenza viruses for intramuscular injection.**Synonyms** Quadrivalent Influenza Vaccine.**Recommended use of the chemical and restrictions on use****Recommended Use** Indicated for active immunization against disease caused by influenza A subtype viruses and influenza 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.

**Label elements****Emergency Overview**

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

**Appearance** Clear**Physical State** Liquid**Odor** Not available

**Hazards not otherwise classified (HNOC)**

Not classified as hazardous substance.

**Other Information**

Not classified as hazardous substance.

**3. COMPOSITION/INFORMATION ON INGREDIENTS****Synonyms** Quadrivalent Influenza Vaccine.

Chemical Name	CAS No.	Weight-%
Recombinant hemagglutinin proteins	N/A	.036
Sodium phosphate-buffered isotonic sodium chloride solution	N/A	q.s. to 100

**4. FIRST AID MEASURES****First aid measures**

<b>Eye Contact</b>	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.
<b>Skin Contact</b>	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.
<b>Inhalation</b>	In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.
<b>Ingestion</b>	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Self-Protection of the First Aider</b>	Do not use mouth-to-mouth methods if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or another proper respiratory medical device.

**Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	Common adverse effects from the vaccine include tenderness and pain at injection-site, headaches, fatigue, myalgia and arthralgia.
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**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** None known.

**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 up 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 other hazardous materials with occupational exposure limits established by the region specific regulatory.

**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**

**Eyeface Protection** In laboratory or industrial settings, safety glasses with side shields are recommended.

<b>Skin and Body Protection</b>	In laboratory or industrial settings, gloves and lab coats are recommended.
<b>Respiratory Protection</b>	Used as supplied, general room ventilation is acceptable and no special respiratory protection is needed when administering this vaccine.
<b>General Hygiene Considerations</b>	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

<b>Physical State</b>	Liquid.	<b>Odor</b>	Not available.
<b>Appearance</b>	Clear liquid.		
<b>Color</b>	Colorless.	<b>Odor Threshold</b>	Not available.

<u>Property</u>	<u>Values</u>	<u>Remarks</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	Not available.	
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 processing.

**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

**Acute Toxicity** No data available.

**Information on toxicological effects**

**Symptoms** Common adverse effects from the vaccine include tenderness and pain at injection-site, headaches, fatigue, myalgia and arthralgia.

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

**Skin Corrosion/Irritation** No impact known or expected under normal use.

**Serious Eye Damage/Eye Irritation** No impact known or expected under normal use.

**Sensitization** No impact known or expected under normal use.

**Germ Cell Mutagenicity** Flublok Quadrivalent has not been evaluated for mutagenic potential in animals or humans.

**Carcinogenicity** Flublok Quadrivalent has not been evaluated for carcinogenic effects in animals or humans.

**Reproductive Toxicity** Available data on Flublok Quadrivalent and Flublok (trivalent formulation) administered to pregnant women are insufficient to inform vaccine-associated risks in pregnant women. It is not known whether Flublok Quadrivalent is excreted in human milk. Data are not available to assess the effects of Flublok (trivalent formulation) or Flublok Quadrivalent on the breastfed infant or on milk production/excretion.

**Developmental Toxicity** There were no developmental studies of Flublok Quadrivalent formulation performed in animals. The developmental effects of Flublok (trivalent formulation) are relevant to Flublok Quadrivalent because both vaccines are manufactured using the same process and have overlapping compositions. A developmental study of Flublok (trivalent formulation) has been performed in rats administered 0.5 mL divided of Flublok (trivalent formulation) prior to mating and during gestation. This study revealed no evidence of harm to the fetus due to Flublok (trivalent formulation).

**Teratogenicity** No evidence of teratogenic potential.

**STOT - Single Exposure** Not classified.

**STOT - Repeated Exposure** Not classified.

**Aspiration Hazard** No data 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**

<b>Disposal of Wastes</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
<b>Contaminated Packaging</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
<b>US EPA Waste Number</b>	Not available.
<b>California Hazardous Waste Codes</b>	Not available.

**14. TRANSPORT INFORMATION**

<b><u>DOT</u></b>	Not regulated.
<b><u>TDG</u></b>	Not regulated.
<b><u>MEX</u></b>	Not regulated.
<b><u>ICAO (air)</u></b>	Not regulated.
<b><u>IATA</u></b>	Not regulated.
<b><u>IMDG</u></b>	Not regulated.
<b><u>RID</u></b>	Not regulated.
<b><u>ADR</u></b>	Not regulated.
<b><u>AND</u></b>	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 subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

<b>Acute Health Hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire Hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No

Reactive Hazard No

**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). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

No component is on the Proposition 65 list.

**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**

<b>Issue Date</b>	2-Oct-2017
<b>Prepared by</b>	IES Engineers
<b>Revision Date</b>	07-July-2021
<b>Revision Note</b>	Updated Revision Date and Version. 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**