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

Emergency telephone number

Company Phone Number 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.

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

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 not breathing, provide artificial respiration. 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 immediately. 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 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

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

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

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 this 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 liquid.	**Odor**	Not available.
Color	Colorless.	**Odor Threshold**	Not available.

Property	**Values**	**Remarks**
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 No reproductive toxicological effects in animals.

Developmental Toxicity In a developmental toxicity study, female rats were administered 0.5 mL divided of Flublok (trivalent formulation) by intramuscular injection twice prior to mating (35 days and 14 days prior to mating) and on gestation Day 6. No vaccine-related fetal malformations or variations and no adverse effects on pre-weaning development were observed in the study.

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

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 available.
California Hazardous Waste Codes	Not available.

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.
AND	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

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 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

Issue Date	2-Oct-2017
Prepared by	IES Engineers
Revision Date	Not applicable.
Revision Note	Not applicable.

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