

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**

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.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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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.	Odor	Not available.
Appearance	Clear liquid.	Odor Threshold	Not available.
Color	Colorless.		

<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

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

<u>DOT</u>	Not regulated.
<u>TDG</u>	Not regulated.
<u>MEX</u>	Not regulated.
<u>ICAO (air)</u>	Not regulated.
<u>IATA</u>	Not regulated.
<u>IMDG</u>	Not regulated.
<u>RID</u>	Not regulated.
<u>ADR</u>	Not regulated.
<u>AND</u>	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	04-Aug-2020
Revision Note	Updated Section 1:Sanofi Pasteur 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