SECTION 1. IDENTIFICATION

Product name: Fluzone High-Dose, Influenza Vaccine

Synonyms: 372 Trivalent Influenza Vaccine, Types A&B, High Dose

Manufacturer or supplier's details

Company : **Sanofi**

Street address : 46-48 avenue de la Grande-Armée
(FR) 75017 Paris

Telephone : +33153774000

Telefax : +33153774133

Safety data sheet created by:
Sanofi Global Product Stewardship (product-stewardship-global@sanofi.com)

Emergency telephone number : **+ 33 1 45 42 59 59 (ORFILA)**

Recommended use of the chemical and restrictions on use

Recommended use : Drug product for medical use.
This document, established by Sanofi on a voluntary basis, aims at providing available information on the substances contained in our products and on the related risk management measures.
This document is intended for use in the workplace and shall not be used in place of package inserts or other prescribing information, nor in place of any mandatory document (e.g SDS within the meaning of the REACH Regulation).
Although the information contained in the document has been prepared based on the best of our knowledge and is accurate as of the date shown on the document, such document is provided «as is», without any warranty, either expressed or implied.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

Physical, chemical and toxicological hazards : Avoid contact with skin and eyes

Sanofi hazard bands:

Further information see chapter 16.

Safety : No data available for mixture.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture
Product Description	:	Vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B

Components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice	:	Move out of dangerous area. Take off immediately all contaminated clothing. Get immediate medical advice/ attention.
If inhaled	:	Move to fresh air. Get immediate medical advice/ attention.
In case of skin contact	:	Rinse immediately with plenty of water for at least 15 minutes. Get immediate medical advice/ attention.
In case of eye contact	:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get immediate medical advice/ attention.
If swallowed	:	Get immediate medical advice/ attention. Do NOT induce vomiting. Rinse mouth with water. If a person vomits when lying on his back, place him in the recovery position.
Most important symptoms and effects, both acute and delayed	:	No information available. No information available.
Notes to physician	:	Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	:	Do NOT use water jet.
Hazardous combustion products	:	Carbon oxides
Further information	:	Prevent fire extinguishing water from contaminating surface water or the ground water system. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for firefighters	:	Wear an approved positive pressure self-contained breathing apparatus in addition to standard fire fighting gear.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	No personal respiratory protective equipment normally required. Safety glasses with side-shields Wear suitable gloves. Wear suitable protective clothing. Only qualified personnel equipped with suitable protective

equipment may intervene.

Environmental precautions	:	Prevent further leakage or spillage. Do not let product enter drains.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Sweep up and shovel into suitable containers for disposal. Close and label thoroughly.
Elimination of recovered materials	:	Deliver to the Environmental service of the factory or to any specialized and approved disposal company.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	To avoid ignition of vapours by static electricity discharge, all metal parts of the equipment must be grounded. Keep away from sources of ignition - No smoking.
Advice on safe handling	:	No special handling advice required.
Further information on storage conditions	:	Keep tightly closed in a dry and cool place. Keep away from direct sunlight.
Storage temperature	:	Recommended storage temperature: +2°C to +8°C.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Personal protective equipment

Respiratory protection	:	Usually, no respiratory protection required.
Hand protection		
Material	:	Nitrile rubber
Rate of permeability	:	> 480 min
Glove thickness	:	> 0.1 mm
Remarks	:	The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard EN374. This recommendation applies only to the product stated in this safety data sheet and supplied by us as well as to the purpose specified by us. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves.
Eye protection	:	Safety glasses
Skin and body protection	:	Wear suitable protective clothing.
Protective measures	:	Avoid contact with skin and eyes. A workplace risk assessment must be carried out in order to determine the correct engineering control measures and personal protective equipment.
Hygiene measures	:	When using, do not eat, drink or smoke. Keep away from foodstuffs and beverages. Wash hands before breaks and at the end of workday.

Laboratory

Respiratory protection	:	Usually, no respiratory protection required.
Hand protection	:	Nitrile rubber Layer thickness > 0.11 mm. Breakthrough time > 480 min.
Eye/face protection	:	Safety glasses
Body Protection	:	Wear suitable protective clothing.
Hygiene measures	:	Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solution
Appearance	:	liquid
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	not determined
Melting point/range	:	not determined
Boiling point	:	not determined
Flash point	:	not determined
Vapour pressure	:	not determined
Relative vapour density	:	not determined
Density	:	not determined
Solubility(ies)		
Water solubility	:	not determined
Solubility in other solvents	:	not determined
Partition coefficient: n-	:	not determined

octanol/water

Ignition temperature	:	not determined
Auto-ignition temperature	:	not determined
Decomposition temperature	:	not determined
Lower explosion limit	:	not determined
Upper explosion limit	:	not determined
Minimum ignition energy	:	not determined
Viscosity		
Viscosity, dynamic	:	not determined
Viscosity, kinematic	:	not determined
Impact sensitivity	:	not determined

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None known.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	None known.
Incompatible materials	:	None known.
Hazardous decomposition products	:	In case of fire hazardous decomposition products may be produced such as: Carbon dioxide (CO2) Carbon monoxide

Sanofi Safety Hazard Band Components (Further information see chapter 16.):

Fluzone High-Dose, Influenza Vaccine	:	No data available for mixture.

SECTION 11. TOXICOLOGICAL INFORMATION

Skin corrosion/irritation

Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Fluzone High-Dose, Influenza Vaccine				No data available for mixture.

Serious eye damage/eye irritation

Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Fluzone High-Dose, Influenza Vaccine				No data available for mixture.

Respiratory or skin sensitisation

Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Fluzone High-Dose, Influenza Vaccine				No data available for mixture.

Carcinogenicity

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Carcinogenicity/Germ cell mutagenicity/Reproductive toxicity - Assessment

Product name (CAS-No.)	Carcinogenicity	Germ cell mutagenicity	Reproductive toxicity	Remarks
Fluzone High-Dose, Influenza Vaccine	not determined	not determined	Reproduction: not determined Teratogenicity: not determined	

STOT - single exposure

Product name (CAS-No.)	Test Type	Exposure routes	Target Organs	Assessment	Remarks
Fluzone High-Dose, Influenza Vaccine	STOT-single exposure				No data available for mixture.

STOT - repeated exposure

Product name (CAS-No.)	Test Type	Exposure routes	Target Organs	Assessment	Remarks
Fluzone High-Dose, Influenza Vaccine	STOT - repeated exposure				No data available for mixture.

Aspiration toxicity

Product name (CAS-No.)	Test Type	Result	Remarks
Fluzone High-Dose, Influenza Vaccine	Aspiration toxicity	No data available for mixture.	

11.2 Information on other hazards

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Product name (CAS-No.)	Test Type	Species	Result	Method	Remarks
Fluzone High-Dose, Influenza Vaccine	Toxicity to fish				No data available for mixture.

Fluzone High-Dose, Influenza Vaccine	Toxicity to daphnia and other aquatic invertebrates				No data available for mixture.
Fluzone High-Dose, Influenza Vaccine	Toxicity to algae/aquatic plants				No data available for mixture.
Fluzone High-Dose, Influenza Vaccine	Toxicity to microorganisms				No data available for mixture.
Fluzone High-Dose, Influenza Vaccine	Toxicity to soil dwelling organisms				No data available for mixture.

12.2 Persistence and degradability

Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Fluzone High-Dose, Influenza Vaccine	Biodegradability				No data available for mixture.

12.3 Bioaccumulative potential

Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Fluzone High-Dose, Influenza Vaccine	Bioaccumulation				No data available for mixture.

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

12.6 Endocrine disrupting properties

12.7 Other adverse effects

Product name (CAS-No.)	Test Type	Result	Remarks
Fluzone High-Dose, Influenza Vaccine	Ozone-Depletion Potential	Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances	This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of contents/ container to an approved waste disposal plant.

Contaminated packaging : Dispose of contents/ container to an approved waste disposal plant.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Formaldehyde	50-00-0	100	

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Formaldehyde	50-00-0	100	

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

DISODIUM HYDROGEN PHOSPHATE	7558-79-4	0.21 %
Formaldehyde	50-00-0	0.08 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

DISODIUM HYDROGEN PHOSPHATE	7558-79-4	0.21 %
Formaldehyde	50-00-0	0.08 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

Formaldehyde	50-00-0

Pennsylvania Right To Know

Water	7732-18-5
DISODIUM HYDROGEN PHOSPHATE	7558-79-4
Formaldehyde	50-00-0

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Formaldehyde	50-00-0

Washington Chemicals of High Concern

Formaldehyde	50-00-0

California Prop. 65

WARNING: This product can expose you to chemicals including Formaldehyde, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 04-23-2024

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / EN

Definition of Sanofi-OEB:
OEB is the occupational exposure band with the following levels:

Occupational Exposure Band	Occupational Exposure Level
OEB 1	> 1000 µg/m³
OEB 2	100 - 1000 µg/m³
OEB 3	10 – 100 µg/m³
OEB 4	1 – 10 µg/m³
OEB 5	< 1 µg/m³

Additional notations may be applied as suffixes to the OEL/OEB and are used to communicate additional information that is not directly indicated by the OEL/OEB classifications. This information is necessary to perform an efficient risk assessment and determine the correct exposure controls. The meanings of the suffixes is explained in this way:

Notation/Suffixes	Danger
G1	Reprotoxic hazard for pregnant women. Exposure below the OEL is acceptable.
G2	Reprotoxic hazard for pregnant women. Exposure even below the OEL is not acceptable.
Sr	Respiratory sensitization hazard with serious potential consequences (anaphylactic reactions).
Sk	Specific dermal hazard (High dermal absorption / Danger of skin sensitization).
Cor	Corrosive compound - Important dermal and ocular hazard If corrosive compounds.

Definition of SHB and EHB:
Substances are classified on a scale from 1, the less hazardous, to 5, the most hazardous, according to their safety properties, eg explosivity, flammability, etc. (SHB) and ecotoxicological properties, eg persistance, ecotoxicity (EHB)