Flucelvax® Novartis Vaccines and Diagnostics
Material Safety Data Sheet
Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS, and European Union Standards

Flucelvax®

Section 1 – Chemical Product and Company

Trade Name: Flucelvax®
Synonyms: Inactivated Influenza Vaccine (Surface Antigen), suspension for Injection

Supplier/ Distributor:
Novartis Vaccines and Diagnostics GmbH
Emil-von-Behring-Straße 76
35041 Marburg Deutschland/Germany

Business Phone:
+49 (0) 6421-39 2998 (9AM–4PM)

Manufacturer:
Novartis Vaccines and Diagnostics GmbH
Emil-von-Behring-Straße 76
35041 Marburg Deutschland/Germany

Business Phone:
+49 (0) 6421-39 2998 (9AM–4PM)

Emergency Phone:
+49 (0) 17 26 74 07 [24 hr]

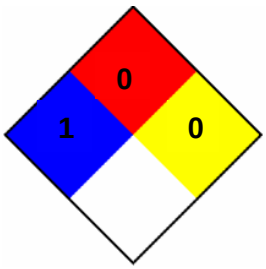
Email Address/Competent Person for MSDS: pedro.diaz@novartis.com
Product Use: Vaccine to prevent influenza
How Supplied: 1-80 liter container, 1-10 milliter Vial, 0.5-5 milliter Syringe

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], and European Union [Regulation (EC) 1907/2006 Annex II] required information is included in appropriate sections based on the U.S. ANSI Z400.1-2004 format. This material has been classified in accordance with the hazard criteria of the countries listed above.

Section 2 – Hazard Identification

EU Labeling/Classification: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC. This material does not meet the definitions of any hazard class as defined by the European Union Council Directive 67/548/EEC or subsequent Directives.

Emergency Overview



Novartis Corporation Laboratory Labeling Codes:

Health: 1 **Flammability: 0** **Reactivity: 0** **Special: None**

Product Description: Flucelvax vaccine is a suspension of protein in water. This material is an opalescent, odorless liquid. **Health Hazards:** Exposure of this material to the eyes may cause irritation. **Flammability Hazards:** This material presents no significant flammability hazards. **Reactivity Hazards:** This material presents no significant reactivity hazards. **Emergency Response Recommendations:** Emergency Responders must wear appropriate personal protective equipment suitable for the situation to which they are responding.

Numbering Guidelines: Based upon a nationally recognized color-coded 0-4 scale: Blue represents Health, Red represents flammability, Yellow represents reactivity and White represents a "special" hazard. 0 represents no hazard and 4 represents the most severe hazard for each category. Examples one might see in the "special" category include CA=potential carcinogen, COR=corrosive, I=irritant, T=toxic, OXY=Oxidizer, PF=Peroxide Former, W=Water reactive, SEN=sensitizing agent, REP=reproductive hazard, and TER=harmful to the fetus

Section 3 – Composition and Information on Ingredients

The vaccine is a sterile parenteral for intramuscular use. It is a purified split-virus preparation propagated in cell culture. It does not contain any live virus particles and cannot cause influenza. The active ingredients are purified proteins that have been isolated from the surfaces of three strains of influenza virus. These strains chosen vary between Flu seasons although the differences present no difference to the handling of the product.

CHEMICAL NAME	CAS #	EINECS #	% w/w	EU CLASSIFICATION FOR COMPONENTS
Flu Cell Culture Proteins			0.001–0.009	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Purified Water and other components present in less than 1.0% concentration in this product (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens).			Balance	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.

See Section 16 for full text of Risk and Safety Phrases

Section 4 – First Aid Measures

Persons who are exposed to this material should seek medical attention if any adverse health effects occur. In the event medical attention is sought, the physician or health care professional should receive a copy of this material's label and this MSDS.

Skin: In the event of skin contamination, wash contaminated area with soap and water.

Eyes: If mists, sprays, or splashes of this material enter the eyes, rinse the affected eyes with flowing water.

Inhalation: Inhalation is not anticipated to be a significant route of overexposure.

Ingestion: Ingestion is not anticipated to be a significant route of overexposure.

Injection: In the event of accidental injection, wash contaminated area with soap and water. The requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) may be applicable.

Medical Conditions Aggravated By Exposure: No specific medical conditions are known to be aggravated by exposure to this material.

Recommendations To Physicians: This material is not expected to cause clinical symptoms. If such symptoms occur, treat the symptoms, while alleviating the cause.

Section 5 – Fire-Fighting Measures

Flash Point: Not applicable.

Autoignition Temperature: Not applicable.

Flammable Limits (in air by volume, %):

UEL: Not applicable. **LEL:** Not applicable.

Fire Extinguishing Materials: In the event of a fire, use suppression methods for surrounding materials, including water spray, halon, carbon dioxide, any 'ABC' class, dry chemical, foam.

Fire Extinguishing Materials Not to Be Used: None known.

Unusual Fire and Explosion Hazards: When involved in a fire, this material may decompose and produce carbon oxides, nitrogen oxides, mercury compounds, and a variety of other compounds.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire-Fighting Procedures: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment

NFPA Rating: HEALTH = 1 FIRE = 0 INSTABILITY = 0 Special= None

Section 6 – Accidental Release Measures

Spill and Leak Response:

Cleanup of Small Spills. Small spills of this material (1 vial) outside a hood should be cleaned immediately by personnel wearing gowns and double latex or nitrile disposable gloves and eye protection. The spill areas should be cleaned three times using a detergent solution and then rinsed with water.

Cleanup of Large Spills. For larger spills of this material (a case of vials, 1–2 Liters), pick up or sweep up spilled vials. Be sure not to damage vials and generate airborne mists or sprays. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of airborne mists or sprays being generated. The dispersal of particles into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Proper protective equipment should be used, including double latex or nitrile gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator. All contaminated surfaces should be thoroughly cleaned with detergent solution and then rinsed with clean water. All contaminated materials should be disposed of according to appropriate hazardous waste regulations.

Section 6 – Accidental Release Measures (Continued)

Spill and Leak Response (continued):

Spills in Hoods. Decontamination of all interior hood surfaces may be required after the above procedures have been followed. If the filter of a hood is contaminated, the unit must be labeled "Do not use—contaminated" and the filter must be changed and disposed of properly as soon as possible by trained personnel wearing protective equipment. Protective goggles should be cleaned with an alcohol wipe after the cleanup.

Clearly labeled spill kits should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12 x 12) of absorbent material, 250-mL and 1-liter spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be incineratable. Finally, the kit should contain two large waste-disposal bags. Avoid generating airborne mists or sprays of this material during spill response procedures. Decontaminate the area of the spill thoroughly. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations). Dispose of recovered material and report spill per regulatory requirements.

Section 7 – Handling and Storage

The following storage and handling practices are recommended.

Work Practices and Hygiene Practices: As with other chemical-containing products, avoid getting this material ON YOU or IN YOU. Do not eat, smoke or drink while handling this material. Wash thoroughly after handling this material or equipment and containers that contained this material. In addition, smokers who do not take simple protective measures such as gloving and hand washing may take in additional amounts of this material orally through contaminated cigarettes, resulting in exposure. Consistent with the OSHA Bloodborne Pathogen regulation (29 CFR 1910.1030), observe Universal Precautions while using this product. Place used or product-contaminated hypodermic needles and syringes in a rigid “Sharps” container. Do not recap or clip used or product-contaminated hypodermic needles. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations of high risk associated with the use of this product include the following:

- Manual manipulation (measuring, transferring, etc.) of liquid drug product; and
- Opening ampoules.

Use of this product should meet the following provisions:

- Work should be performed in a designated area for working with hazardous drugs or potent compounds;
- Containment devices, such as a Biological Safety Cabinet, Ventilated Enclosures should be used;
- Contaminated waste must be properly handled; and
- Work areas must be regularly decontaminated.

Storage and Handling Practices: Employees must be trained to properly use this material. Special attention must be paid to avoid releasing airborne mists or sprays of this material in areas in which it is handled or used. Ensure vials are properly labeled. Store at 2°C to 8°C (36 °F to 46°F). Avoid freezing and excessive heat. Frozen/Previously frozen material should not be used. Store away from incompatible materials (see Section 10, Stability and Reactivity). Protect from light. Disposal of wastes contaminated by this material must be in covered receptacles.

Specific Use(s): This material is for use as a human vaccine. Follow all industry standards for use of this material.

Section 8 – Exposure Controls – Personal Protection

This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(ii). Drugs are exempt from this requirement as determined by the Occupational Safety and Health Administration (OSHA) and cited in 29 CRF 1910.1200(b)(5)(ii).

The following exposure controls and personal protection are recommended.

Ventilation, Engineering, and Occupational Exposure Controls: No special ventilation or engineering controls are required.

Exposure Limits/Guidelines:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Flu Cell Culture Proteins		NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established.

Section 8 – Exposure Controls – Personal Protection (Continued)

International Occupational Exposure Limits: Currently, there are no international occupational exposure limits established for components of this product.

Respiratory Protection: Respiratory protection is not generally needed when using this material. If respiratory protection is needed, use only protection authorized in the U.S. Federal OSHA Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-02, the European Standard EN 529:2005, and EU member state standards. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Safety goggles. Use goggles or safety glasses for spill response, as stated in Section 6 (Accidental Release Measures) of this MSDS. If necessary, refer to U.S. OSHA 29 CFR 1910.133, the European Standard CR 13464:1999, or the Canadian CSA Standard Z94.3-07, *Industrial Eye and Face Protectors*.

Hand Protection: Nitrile, Latex, or other lightweight gloves. Use triple gloves for spill response. If necessary, refer to U.S. OSHA 29 CFR 1910.138, appropriate Standards of Canada, or the European Standard CEN/TR 15419:2006.

Body Protection: No special protection required. If necessary, refer to the OSHA Technical Manual (Section VII: Personal Protective Equipment) or appropriate Standards of Canada, the European Standard CEN/TR 15419:2006

Environmental Exposure Controls: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

Section 9 – Physical and Chemical Properties

Appearance and Color: This material is an opalescent, odorless liquid.
How to Detect This Substance (warning properties): There are no distinguishing characteristics associated with this material.
Boiling Point: Not established.
Melting Point: Not established.
Flash Point: Not applicable.
Flammability: Not flammable.
Explosive Properties: Not explosive.
Oxidizing Properties: Not an oxidizer.
Vapor Pressure, mm Hg @ 20°C: Not established.
Specific Gravity: Approx. 1
Solubility: Not established.
Solubility in Water: Soluble.
Relative Vapor Density (air = 1): Not established.
Evaporation Rate (nBuAc = 1): Not established.
Odor Threshold: Odorless.
pH: Not established.
Coefficient Water/Oil Distribution: Not established.

Section 10 – Stability and Reactivity

Stability: Stable.
Decomposition Products: Combustion: Carbon oxides, nitrogen oxides, mercury compounds, and a variety of other compounds. Hydrolysis: None known.
Incompatibility: Water-reactive materials.
Hazardous Polymerization: Will not occur.
Conditions to Avoid: Contact with incompatible materials.

Section 11 – Toxicological Information

Symptoms of Overexposure: The health information provided below is pertinent to employees using this material in an occupational setting.

Inhalation: No human or animal exposure data are available for this material. Inhalation is not anticipated to be a significant route of exposure.

Contact with Skin or Eyes: No human or animal exposure data are available for this material. Exposure of this material to the eyes may cause irritation.

Skin Absorption: No human or animal exposure data are available for this material.

Ingestion: No human or animal exposure data are available for this material. Ingestion is not anticipated to be a significant route of exposure.

Section 11 – Toxicological Information (Continued)

Injection: Injection of this product, due to puncture by a contaminated object, may cause redness and soreness, fever, fatigue, and aches. See 'Sensitization to the Product' in this section for further information.

Acute: Accidental injection of this product may cause redness or soreness at the site of injection, fever, fatigue, and aches.

Chronic: No human or animal exposure data are available for this material.

Target Organs: Eyes (contact).

Toxicity Data: There are no components of this product present in greater than 1% concentration.

Cancer Agent: The components of this material are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

Irritancy of Product: No human or animal exposure data are available for this material.

Sensitization to the Product: No human or animal exposure data are available for this material.

Reproductive Toxicity Information: Listed below is information concerning the effects of this material on the human reproductive system.

Mutagenicity: Unknown; no studies have been performed.

Embryotoxicity: Unknown; no studies have been performed.

Teratogenicity: One study of influenza vaccination of >2,000 pregnant women demonstrated no adverse fetal effects associated with influenza vaccine.

Reproductive Toxicity: Unknown; no studies have been performed.

ACGIH Biological Exposure Indices: Currently, there are not ACGIH Biological Exposure Indices (BEIs) determined for the components of this product.

Section 12 – Ecological Information

All Work Practices Should be Aimed at Minimizing Environmental Releases

Mobility: This material has not been tested for mobility in soil.

Persistence and Biodegradability: This material will degrade upon exposure to light. It is expected that some biodegradation will occur to this material; however, no specific information is known.

Bio-Accumulation Potential: This material has not been tested for bio-accumulation potential.

Ecotoxicity: This material has not been tested for aquatic or animal toxicity. All release to terrestrial, atmospheric, and aquatic environments should be avoided.

Other Adverse Effects: The components if this product are not been listed as compounds that have ozone depletion potential.

Section 13 – Disposal Considerations

Disposal Methods: Do NOT dispose of any solution of this material by pouring down the drain. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This material, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

Disposal Containers: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

Precautions to be Followed During Waste Handling: Wear proper protective equipment when handling waste materials.

U.S. EPA Waste Number: Not applicable.

EWC Waste Code: Wastes from natal care, diagnosis, treatment, or prevention of disease in humans: chemicals consisting of or containing dangerous substances: 18-01-06

Section 14 – Transportation Information

U.S. Department of Transportation Regulations: This material is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

Transport Canada, Transportation of Dangerous Goods Regulations: This material is NOT classified as dangerous goods, per regulations of Transport Canada.

International Air Transport Association Designation: This material is NOT classified as dangerous goods, per rules of IATA.

Section 14 – Transportation Information (Continued)

International Maritime Organization (IMO): This material is NOT classified as dangerous goods, per rules of the IMO. **Marine Pollutant:** No component of this material is designated by the IMO to be a Marine Pollutant.

European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR): This material is NOT classified by the United Nations Economic Commission for Europe to be dangerous goods.

Section 15 – Regulatory Information

Additional United States Regulations:

SARA Reporting Requirements: Components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

SARA 302 Extremely Hazardous Threshold Planning Quantity (TPQ): Not applicable.

SARA 304 Extremely Hazardous Reportable Quantity (RQ): Not applicable.

CERCLA: Not applicable.

TSCA: This product is regulated by the Food and Drug Administration; it is exempt from the requirements of TSCA.

Other U.S. Federal Regulations: Based on the use of this product, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) are applicable.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): The components of this product are not listed by the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Proposition 65).

Additional Canadian Regulations:

Canadian DSL/NDSL Inventory Status: This product is regulated by the Food and Drug Administration of Health Canada; it is exempt from the requirements of CEPA.

Other Canadian Regulations: Not applicable.

Canadian Environmental Protection Act (CEPA) Priority Substances Lists: The components of this material are not on the CEPA Priority Substances Lists.

Canadian WHMIS Classification and Symbols: Not applicable.

Additional European Union Regulations:

Labeling and Classification: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC. This material does not meet the definitions of any hazard class as defined by the European Union Council Directive 67/548/EEC or subsequent Directives.

Classification: Not applicable.

Risk Phrases: Not applicable.

Safety Phrases: Not applicable.

Hazard Symbol: Not applicable.

Information for Components:

Flu Cell Culture Proteins: An official classification has not been published in European Commission Directives for these components.

Section 16 – Other Information

Prepared by:

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Glossary:
ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EU = European Union
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IMO = International Maritime Organization
LC_{50} = Lethal Concentration at 50 % of test population (gases and vapors)
LD_{50} = Lethal Dose at 50 % of test population
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NE = Not Established
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TD_{LO} = Toxic Dose (lowest) that caused a symptom
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)