

# SAFETY DATA SHEET



Revision date: 16-Jan-2014

Version: 2.0

Page 1 of 7

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** FluSure® XP (H1N2)

**Trade Name:** FluSure™ XP  
**Synonyms:** Swine Influenza Vaccine, H1N1, H1N2 and H3N2, Killed Virus  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary Vaccine

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

**Appearance:** Veterinary vaccine pellets plus a liquid adjuvanted preparation

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Not Classified  
**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

**Short Term:** In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

### Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## SAFETY DATA SHEET

Material Name: FluSure® XP (H1N2)  
Revision date: 16-Jan-2014

Page 2 of 7  
Version: 2.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Gentamicin	1403-66-3	215-765-8	Not Listed	Not Listed	##

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Amphigen	MIXTURE	Not Listed	Not Listed	Not Listed	*
Swine Influenza Virus A, strain H1N1	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Swine Influenza Virus A, strain H3N2	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Swine Influenza Virus A, strain H1N2	Not Assigned	Not Listed	Not Listed	Not Listed	*

**Additional Information:**

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

## SAFETY DATA SHEET

Material Name: FluSure® XP (H1N2)  
Revision date: 16-Jan-2014

Page 3 of 7  
Version: 2.0

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. Dike and collect water used to fight fire.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Keep away from heat, sparks, and flame. Use with adequate ventilation. Avoid breathing dust, vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. Avoid accidental injection.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Incompatible Materials:** This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Gentamicin

**Bulgaria OEL - TWA** 0.1 mg/m<sup>3</sup>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Gentamicin

**Zoetis OEB** OEB 2 (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Wear impervious gloves if skin contact is possible.

**Eyes:** Safety glasses or goggles

## SAFETY DATA SHEET

Material Name: FluSure® XP (H1N2)  
Revision date: 16-Jan-2014

Page 4 of 7  
Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Skin:** Wear protective clothing when working with large quantities.  
**Respiratory protection:** If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Pellets plus sterile diluent	<b>Color:</b>	No data available.
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>Solubility:</b>	Soluble: Water (based on components)
<b>pH:</b>	7.0 +/- 1.5
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	>100
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	No data available
<b>Decomposition Temperature (°C):</b>	No data available.

<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	Expected to be negligible
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Specific Gravity:</b>	1.0 +/-0.2
<b>Viscosity:</b>	No data available

<b>Flammability:</b>	
<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	Non-flammable
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Polymerization:</b>	Will not occur

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible Materials:</b>	This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous Decomposition Products:</b>	None expected under normal conditions.

### 11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

## SAFETY DATA SHEET

Material Name: FluSure® XP (H1N2)  
Revision date: 16-Jan-2014

Page 5 of 7  
Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

**General Information:** Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Gentamicin**

Rat Oral LD50 6600 mg/kg  
Rat Subcutaneous LD50 710mg/kg  
Mouse IM LD50 167 mg/kg  
Rat IM LD50 463 mg/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Gentamicin**

Eye Irritation Rabbit Non-irritating

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Gentamicin**

Embryo / Fetal Development Rat Intramuscular 75 mg/kg/day LOAEL Developmental toxicity

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## SAFETY DATA SHEET

Material Name: FluSure® XP (H1N2)  
Revision date: 16-Jan-2014

Page 6 of 7  
Version: 2.0

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

None required

**Amphigen**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed

**Swine Influenza Virus A, strain H1N1**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed

**Swine Influenza Virus A, strain H3N2**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed

**Gentamicin**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4

## SAFETY DATA SHEET

Material Name: FluSure® XP (H1N2)  
Revision date: 16-Jan-2014

Page 7 of 7  
Version: 2.0

### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List 215-765-8

Swine Influenza Virus A, strain H1N2

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List Not Listed

### 16. OTHER INFORMATION

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**