



# MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2011

Version: 1.0

Page 1 of 7

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

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288  
Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd,  
Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

### Material Name: FluSure XP®/RespiSure (H1N2)

**Trade Name:** FluSure™ XP/RespiSure® (H1N2)  
**Synonyms:** Swine Influenza Vaccine, H1N1, H1N2, H3N2, Killed Virus-Mycoplasma Hyopneumoniae Bacterin  
**Chemical Family:** Mixture  
**Intended Use:** Veterinary Vaccine

## 2. HAZARDS IDENTIFICATION

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

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

**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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

**EU Indication of danger:** Not classified

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Mineral oil	8012-95-1	232-384-2	Not Listed	*
Gentamicin	1403-66-3	215-765-8	Not Listed	*

## MATERIAL SAFETY DATA SHEET

Material Name: FluSure XP®/RespiSure (H1N2)  
Revision date: 04-Jan-2011

Page 2 of 7  
Version: 1.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Merthiolate (as mercury)	54-64-8	200-210-4	N; R50/53 R33 T+; R26/27/28	##
--------------------------	---------	-----------	-----------------------------------	----

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Swine Influenza Virus A, strain H1N1	NOT ASSIGNED	Not Listed	Not Listed	*
Swine Influenza Virus A, strain H3N2	NOT ASSIGNED	Not Listed	Not Listed	*
Sorbitan monooleate	1338-43-8	215-665-4	Not Listed	*
Mycoplasma Hypopneumoniae	NOT ASSIGNED	Not Listed	Not Listed	*
Polyoxyethylene (20) sorbitan monooleate	9005-65-6	Not Listed	Not Listed	*
Swine Influenza Virus A, strain H1N2	Not Assigned	Not Listed	Not Listed	*
Amphigen	MIXTURE	Not Listed	Not Listed	*

#### Additional Information:

\* Proprietary

## Trace Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Notes to Physician:</b>	Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	As for primary cause of fire.
<b>Hazardous Combustion Products:</b>	Not known
<b>Fire Fighting Procedures:</b>	Dike and collect water used to fight fire.
<b>Fire / Explosion Hazards:</b>	Not applicable
<b>Additional Information:</b>	This product is a nonflammable aqueous solution. This material is not expected to support combustion.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
---------------------------------------	--

## MATERIAL SAFETY DATA SHEET

Material Name: FluSure XP®/RespiSure (H1N2)  
Revision date: 04-Jan-2011

Page 3 of 7  
Version: 1.0

**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.

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

**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

**General Handling:** Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing dust, vapor or mist.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Mineral oil

ACGIH Threshold Limit Value (TWA)	5 mg/m <sup>3</sup> TWA
ACGIH Threshold Limit Value (STEL)	10 mg/m <sup>3</sup> STEL
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	5 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	5 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Gentamicin

Bulgaria OEL - TWA	Listed
--------------------	--------

#### Merthiolate (as mercury)

ACGIH Threshold Limit Value (TWA)	0.01 mg/m <sup>3</sup> TWA
ACGIH Threshold Limit Value (STEL)	0.03 mg/m <sup>3</sup> STEL
ACGIH - Skin Absorption Designation	Listed
Australia STEL	0.03 mg/m <sup>3</sup>
Australia TWA	0.01 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Bulgaria - Biological Exposure Limit:	Listed
Czech Republic OEL - TWA	Listed

## MATERIAL SAFETY DATA SHEET

Material Name: FluSure XP®/RespiSure (H1N2)  
Revision date: 04-Jan-2011

Page 4 of 7  
Version: 1.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany - Biological Exposure Limit:	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	0.01 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania - Biological Exposure Limit:	Listed
Slovak Republic - Biological Exposure Limit:	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

<b>Engineering Controls:</b>	General room ventilation is adequate unless the process generates dust, mist or fumes.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Wear protective clothing when working with large quantities.
<b>Respiratory protection:</b>	Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Pellets plus sterile diluent	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solubility:</b>	Soluble: Water (based on components)		
<b>pH:</b>	7.0 +/- 1.5		
<b>Boiling Point (°C):</b>	>100		
<b>Vapor Pressure (kPa):</b>	Expected to be negligible		
<b>Specific Gravity:</b>	1.0 +/-0.2		
<b>Flash Point (Liquid) (°C):</b>	Non-flammable		
<b>Polymerization:</b>	Will not occur		

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable
<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.

## MATERIAL SAFETY DATA SHEET

Material Name: FluSure XP®/RespiSure (H1N2)  
Revision date: 04-Jan-2011

Page 5 of 7  
Version: 1.0

### 10. STABILITY AND REACTIVITY

**Hazardous Decomposition Products:** None expected under normal conditions.

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The information included in this section describes the potential hazards of the individual ingredients.

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

##### **Gentamicin**

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

##### **Merthiolate (as mercury)**

Rat Oral LD50 75 mg/kg  
Rat Subcutaneous LD50 98 mg/kg

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

##### **Gentamicin**

Eye Irritation Rabbit Non-irritating

##### **Merthiolate (as mercury)**

Eye Irritation Rabbit Mild

##### **Mineral oil**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

#### 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.

##### **Mineral oil**

**IARC:** Group 3

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Releases to the environment should be avoided. The environmental characteristics of this material have not been fully evaluated.

# MATERIAL SAFETY DATA SHEET

Material Name: FluSure XP®/RespiSure (H1N2)  
Revision date: 04-Jan-2011

Page 6 of 7  
Version: 1.0

## 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. This product contains trace quantities of mercury and may qualify as a RCRA Hazardous Waste. Status should be confirmed using the EPA Toxicity Characteristic Leaching Procedure (TCLP).

## 14. TRANSPORT INFORMATION

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

## 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

**OSHA Label:**  
Non-hazardous in accordance with international standards for workplace safety.

### Canada - WHMIS: Classifications

**WHMIS hazard class:**

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

### **Sorbitan monooleate**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Listed
<b>Australia (AICS):</b>	Listed
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	215-665-4

### **Mineral oil**

<b>Inventory - United States TSCA - Sect. 8(b)</b>	Listed
<b>Australia (AICS):</b>	Listed
<b>EU EINECS/ELINCS List</b>	232-384-2

### **Gentamicin**

<b>California Proposition 65</b>	Aminoglycosides- developmental
----------------------------------	--------------------------------

## MATERIAL SAFETY DATA SHEET

Material Name: FluSure XP®/RespiSure (H1N2)  
Revision date: 04-Jan-2011

Page 7 of 7  
Version: 1.0

### 15. REGULATORY INFORMATION

<b>Australia (AICS):</b>	Listed
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	215-765-8
<b>Polyoxyethylene (20) sorbitan monooleate</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Listed
<b>Australia (AICS):</b>	Listed
<b>Merthiolate (as mercury)</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	1.0% Supplier notification limit
<b>California Proposition 65</b>	Developmental
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Listed
<b>Australia (AICS):</b>	Listed
<b>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</b>	Use restricted. See item 18.
<b>EU EINECS/ELINCS List</b>	200-210-4

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R33 - Danger of cumulative effects.

R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Prepared by:** Product Stewardship Hazard Communications  
Pfizer Global Environment, Health, and Safety Operations

Pfizer 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**