

SAFETY DATA SHEET



1. Identification

Product identifier	FluSure XP/RespiSure One
Other means of identification	
Synonyms	FluSure™ XP/RespiSure® * Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus-Mycoplasma Hypopneumoniae Bacterin
Recommended use	Veterinary vaccine
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.

Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Other hazards None known.

Supplemental information Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Amphigen (Mineral oil / Soy lecithin)		8042-47-5	5
Gentamicin		1403-66-3	##
Mycoplasma Hyopneumoniae		Not assigned	*
Swine Influenza Virus A, strain H1N1		Not assigned	*
Swine Influenza Virus A, strain H3N2		Not assigned	*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments ## Trace
* Non-hazardous Ingredients

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.
Indication of immediate medical attention and special treatment needed	Treat symptomatically. Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.
General information	For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. Avoid accidental injection. Wash thoroughly after handling. When using, do not eat, drink or smoke. Wear personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store away from direct sunlight. @ 2 - 7°C (36 - 45°F). Do not freeze. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)	STEL	10 mg/m ³	Mist.
	TWA	5 mg/m ³	Mist.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)	TWA	1 mg/m ³	Mist.

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value	Form
Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value	Form
Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)	STEL	10 mg/m ³	Mist.
	TWA	5 mg/m ³	Mist.

Biological limit values No biological exposure limits noted for the ingredient(s).

Control banding approach Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Wear impervious gloves if skin contact is possible.

Other Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. 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. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

Thermal hazards Not applicable.

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 to remove contaminants.

9. Physical and chemical properties

Appearance Freeze-dried pellet plus liquid bacterin

Physical state Solid, Liquid.

Form Solid. Liquid.

Colour Not available.

Odour Not available.

Odour threshold Not available.

pH 6 - 8

Melting point/freezing point Not available.

Initial boiling point and boiling range > 100 °C (> 212 °F)

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit – upper (%) Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) 100 %

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidising properties Not oxidising.

Specific gravity 0.8 - 1.2

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Sunlight. High temperatures. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

Incompatible materials Strong oxidising agents. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	Prolonged skin contact may cause temporary irritation.
Amphigen (Mineral oil / Soy lecithin)	Species: Rabbit Severity: Non-irritating
Eye contact	Direct contact with eyes may cause temporary irritation.
Amphigen (Mineral oil / Soy lecithin)	Species: Rabbit Severity: Non-irritating
Gentamicin	Species: Rabbit Severity: Non-irritating

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
Chronic		
Oral		
NOAEL	Rat	1800 mg/kg/day, 90 days Liver
Gentamicin (CAS 1403-66-3)		
Acute		
Intramuscular		
LD50	Mouse	167 mg/kg
	Rat	463 mg/kg
Oral		
LD50	Rat	6600 mg/kg
Subcutaneous		
LD50	Rat	710 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye contact		
Amphigen (Mineral oil / Soy lecithin)	Species: Rabbit Severity: Non-irritating	
Gentamicin	Species: Rabbit Severity: Non-irritating	

Respiratory or skin sensitisation

Respiratory sensitisation	Not a respiratory sensitizer.
Skin sensitisation	This product is not expected to cause skin sensitisation.

Skin sensitisation

Amphigen (Mineral oil / Soy lecithin)

Species: Guinea Pig

Severity: negative

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Amphigen (Mineral oil / Soy lecithin)

In Vitro Bacterial Mutagenicity (Ames)

Result: negative

Species: Salmonella

In Vitro Mammalian Cell Mutagenicity

Result: negative

Species: Mouse Lymphoma

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACGIH Carcinogens

Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)

A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)

Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)

3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects.

Developmental effects

Gentamicin

75 mg/kg/day Embryo / Fetal Development, Developmental toxicity

Result: LOAEL

Species: Rat

Organ: Intramuscular

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Not classified.

Aspiration hazard

Not an aspiration hazard.

Further information

Allergic reactions are possible. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

12. Ecological information**Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components**Species****Test results**

Amphigen (Mineral oil / Soy lecithin) (CAS 8042-47-5)

LC50

Lepomis macrochirus (Bluegill Sunfish) > 10000 mg/l, 96 Hours

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	None known.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

Canadian regulations	This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.	
Controlled Drugs and Substances Act	Not regulated.	
Export Control List (CEPA 1999, Schedule 3)	Not listed.	
Greenhouse Gases	Not listed.	
Precursor Control Regulations	Not regulated.	
International regulations		
Stockholm Convention	Not applicable.	
Rotterdam Convention	Not applicable.	
Kyoto protocol	Not applicable.	
Montreal Protocol	Not applicable.	
Basel Convention	Not applicable.	

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date	04-April-2017
Version No.	01
Disclaimer	Zoetis Inc. believes 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. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	Product and Company Identification: Physical States Composition / Information on Ingredients: Ingredients