



MATERIAL SAFETY DATA SHEET

Revision date: 11-Apr-2008

Version: 1.0

Page 1 of 12

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

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

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

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

Material Name: FarrowSure GOLD

Trade Name:	FarrowSure GOLD
Chemical Family:	Mixture
Intended Use:	Veterinary product used as Veterinary Vaccine

2. HAZARDS IDENTIFICATION

Appearance: Liquid solution
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.
Contains formaldehyde: potential cancer hazard

Additional Hazard Information:
Short Term: May cause eye, skin and respiratory tract irritation (based on components) 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.

EU Indication of danger: Irritant

EU Hazard Symbols:
Xi



EU Risk Phrases:
R43 - May cause sensitization by skin contact.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 2 of 12
Version: 1.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Gentamicin	1403-66-3	215-765-8	Not Listed	##
Formaldehyde	50-00-0	200-001-8	C;R34 Carc. Cat.3;R40 R43 T;R23/24/25	0.2-0.5
Merthiolate (as mercury)	54-64-8	200-210-4	N; R50/53 R33 T+; R26/27/28	##
Aluminum hydroxide	21645-51-2	244-492-7	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Erysipelothrix rhusiopathiae	NOT ASSIGNED	Not listed	Not Listed	*
Leptospira canicola	NOT ASSIGNED	Not listed	Not Listed	*
Leptospira grippotyphosa	NOT ASSIGNED	Not listed	Not Listed	*
Leptospira hardjo	NOT ASSIGNED	Not listed	Not Listed	*
Leptospira icterohaemorrhagiae	NOT ASSIGNED	Not listed	Not Listed	*
Leptospira pomona	NOT ASSIGNED	Not listed	Not Listed	*
Porcine Parvovirus	NOT ASSIGNED	Not listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	>90%
Amphigen base	NOT ASSIGNED	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

Eye Contact:	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin Contact:	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
Ingestion:	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation:	Get medical attention immediately. Remove to fresh air. If not breathing, give artificial respiration.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	As for primary cause of fire.
Hazardous Combustion Products:	Not known
Fire Fighting Procedures:	Dike and collect water used to fight fire.

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 3 of 12
Version: 1.0

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

6. ACCIDENTAL RELEASE MEASURES

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

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 vapor or mist. Use appropriate personal protective equipment.

Storage Conditions: Store under refrigeration in closed container.

Storage Temperature: 2-7°C

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 4 of 12
Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Gentamicin

Bulgaria OEL - TWA = 0.1 mg/m³ TWA

Formaldehyde

ACGIH Ceiling Threshold Limit: = 0.3 ppm Ceiling

ACGIH - Sensitizer Designation Sensitizer

Australia STEL = 2 ppm STEL
= 2.5 mg/m³ STEL

Australia TWA = 1 ppm TWA
= 1.2 mg/m³ TWA

Austria OEL - MAKs = 0.5 ppm MAK
= 0.6 mg/m³ MAK

Bulgaria OEL - TWA = 1.0 mg/m³ TWA

Czech Republic OEL - TWA = 0.5 mg/m³ TWA

Estonia OEL - TWA = 0.5 ppm TWA
= 0.6 mg/m³ TWA

Finland OEL - TWA = 0.3 ppm TWA
= 0.37 mg/m³ TWA

France OEL - TWA = 0.5 ppm VME

Greece OEL - TWA = 2 ppm TWA
= 2.5 mg/m³ TWA

Hungary OEL - TWA = 0.6 mg/m³ TWA

Ireland OEL - TWAs = 2 ppm TWA
= 2.5 mg/m³ TWA

Latvia OEL - TWA = 0.5 mg/m³ TWA

Lithuania OEL - TWA = 0.5 ppm IPRV
= 0.6 mg/m³ IPRV

Netherlands OEL - TWA = 1 ppm MAC
= 1.5 mg/m³ MAC

OSHA - Final PELs - TWAs: = 0.75 ppm TWA

OSHA - Specifically Regulated Chemicals = 0.5 ppm Action Level
= 0.75 ppm TWA
= 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR 1910.1048

Poland OEL - TWA = 0.5 mg/m³ NDS

Romania OEL - TWA = 1 ppm TWA
= 1.20 mg/m³ TWA

Slovakia OEL - TWA = 0.3 ppm TWA
= 0.37 mg/m³ TWA

Slovenia OEL - TWA = 0.5 ppm TWA
= 0.62 mg/m³ TWA

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 5 of 12
Version: 1.0

Sweden OEL - TWAs	= 0.5 ppm LLV = 0.6 mg/m ³ LLV	
Merthiolate (as mercury)		
ACGIH Threshold Limit Value (TWA)	= 0.01 mg/m ³ TWA	
ACGIH Threshold Limit Value (STEL)	= 0.03 mg/m ³ STEL	
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route	
Australia STEL	= 0.03 mg/m ³ STEL	
Australia TWA	= 0.01 mg/m ³ TWA	
Austria OEL - MAKs	= 0.01 mg/m ³ MAK	except methylmercury
Belgium OEL - TWA	= 0.01 mg/m ³ TWA	
Bulgaria OEL - TWA	= 0.01 mg/m ³ TWA	
Czech Republic OEL - TWA	= 0.01 mg/m ³ TWA	
Denmark OEL - TWA	= 0.01 mg/m ³ TWA = 0.05 mg/m ³ TWA	except Alkyl compounds
Estonia OEL - TWA	= 0.01 mg/m ³ TWA = 0.03 mg/m ³ TWA	
Finland OEL - TWA	= 0.01 mg/m ³ TWA	
France OEL - TWA	= 0.01 mg/m ³ VME	
Greece OEL - TWA	= 0.01 mg/m ³ TWA = 0.1 mg/m ³ TWA	
Hungary OEL - TWA	= 0.01 mg/m ³ TWA	
Ireland OEL - TWAs	= 0.01 mg/m ³ TWA	
Lithuania OEL - TWA	= 0.01 mg/m ³ IPRV = 0.03 mg/m ³ IPRV	except Alkaline
Netherlands OEL - TWA	= 0.01 mg/m ³ MAC	
OSHA - Final PELs - TWAs:	= 0.01 mg/m ³ TWA	
Poland OEL - TWA	= 0.01 mg/m ³ NDS	
Portugal OEL - TWA	= 0.01 mg/m ³ TWA	
Slovakia OEL - TWA	= 0.01 mg/m ³ TWA	
Slovenia OEL - TWA	= 0.01 mg/m ³ TWA	
Spain OEL - TWA	= 0.01 mg/m ³ VLA-ED	
Sweden OEL - TWAs	= 0.01 mg/m ³ LLV	
Aluminum hydroxide		
ACGIH OELs - Notice of Intended Changes	Listed	
Bulgaria OEL - TWA	= 1.5 mg/m ³ TWA = 10.0 mg/m ³ TWA	
Czech Republic OEL - TWA	= 10.0 mg/m ³ TWA	except for gamma Al ₂ O ₃
Latvia OEL - TWA	= 6 mg/m ³ TWA	
Lithuania OEL - TWA	= 6 mg/m ³ IPRV	
Poland OEL - TWA	= 1.2 mg/m ³ NDS = 2.5 mg/m ³ NDS	
Slovakia OEL - TWA	= 1.5 mg/m ³ TWA	

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 6 of 12
Version: 1.0

Skin: Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

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

10. STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

Incompatible Materials: None known

Hazardous Decomposition Products: None expected under normal conditions.

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 7 of 12
Version: 1.0

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 primary hazards are due to the formaldehyde content.

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

Merthiolate (as mercury)

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

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

Formaldehyde

Rat Oral LD50 800 mg/kg

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

Merthiolate (as mercury)

Eye Irritation Rabbit Mild

Gentamicin

Eye Irritation Rabbit Non-irritating

Formaldehyde

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs
90 Day(s) Rat Inhalation Not Specified Lungs
90 Day(s) Monkey Inhalation Not Specified Lungs
9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

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

Formaldehyde

Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity
Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Formaldehyde

In Vitro Bacterial Mutagenicity (Ames) Bacteria Positive

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 8 of 12
Version: 1.0

11. TOXICOLOGICAL INFORMATION

In Vitro Chromosome Aberration Rodent Positive
In Vitro Sister Chromatid Exchange Rodent Positive
In Vivo Chromosome Aberration Not specified Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors
2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

Carcinogen Status: See below

Formaldehyde

IARC: Group 1 (Carcinogenic to Humans)
NTP: Reasonably Anticipated To Be A Carcinogen

OSHA: Present

12. ECOLOGICAL INFORMATION

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

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 9 of 12
Version: 1.0

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:

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). Dispose of waste in accordance with all applicable laws and regulations.

Formaldehyde

RCRA - U Series Wastes

waste number U122

14. TRANSPORT INFORMATION

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

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 10 of 12
Version: 1.0

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S24 - Avoid contact with skin.
S36 - Wear suitable protective clothing.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.
Contains formaldehyde: potential cancer hazard

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Gentamicin

California Proposition 65	Aminoglycosides- developmental
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	215-765-8

Formaldehyde

CERCLA/SARA 313 Emission reporting	= 0.1 % de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 100 lb final RQ = 45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 100 lb EPCRA RQ
California Proposition 65	carcinogen, initial date 1/1/88 (gas)
OSHA - Specifically Regulated Chemicals	= 0.5 ppm Action Level = 0.75 ppm TWA = 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR 1910.1048

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 11 of 12
Version: 1.0

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 6
EU EINECS/ELINCS List	200-001-8
Merthiolate (as mercury)	
CERCLA/SARA 313 Emission reporting	= 1.0 % Supplier notification limit
California Proposition 65	Developmental
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 18.
EU EINECS/ELINCS List	200-210-4
Water, purified	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Aluminum hydroxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	244-492-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R33 - Danger of cumulative effects.

R34 - Causes burns.

R40 - Limited evidence of a carcinogenic effect

R43 - May cause sensitization by skin contact.

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

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

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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 a warranty of any kind, expressed or implied.

MATERIAL SAFETY DATA SHEET

Material Name: FarrowSure GOLD
Revision date: 11-Apr-2008

Page 12 of 12
Version: 1.0

End of Safety Data Sheet