



# MATERIAL SAFETY DATA SHEET

Revision date: 04-Dec-2006

Version: 1.5

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

**Pfizer Animal Health**  
**Pfizer Inc**  
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CHEMTREC (24 hours): 1-800-424-9300

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

**Material Name: Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza3 Vaccine, Modified Live Virus, Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin**

**Trade Name:** PregGuard GOLD(R) FP(TM) 10  
**Chemical Family:** Mixture  
**Intended Use:** Veterinary Vaccine

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Gentamicin	1403-66-3	215-765-8	##
Formaldehyde	50-00-0	200-001-8	0.1 - 1.0
Merthiolate (as mercury)	54-64-8	200-210-4	##

Ingredient	CAS Number	EU EINECS List	%
Bovine Parainfluenza3	NOT ASSIGNED	Not listed	*
Bovine Rhinotracheitis	NOT ASSIGNED	Not listed	*
Bovine Virus Diarrhea	NOT ASSIGNED	Not listed	*
Campylobacter fetus	NOT ASSIGNED	Not listed	*
Leptospira canicola	NOT ASSIGNED	Not listed	*
Leptospira grippotyphosa	NOT ASSIGNED	Not listed	*
Leptospira hardjo	NOT ASSIGNED	Not listed	*
Leptospira icterohaemorrhagiae	NOT ASSIGNED	Not listed	*
Leptospira pomona	NOT ASSIGNED	Not listed	*
Water, purified	7732-18-5	231-791-2	>90

### Additional Information:

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Liquid solution in multiple-dose vials  
**Signal Word:** WARNING

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### Statement of Hazard:

Contains formaldehyde: potential cancer hazard.  
May cause sensitization of the skin and respiratory system.  
May cause eye, skin and respiratory tract irritation.

### Additional Hazard Information:

#### Short Term:

May cause eye and skin irritation. May cause allergic reaction . 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:



### EU Risk Phrases:

R43 - May cause sensitization by skin contact.

### 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.

## 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:

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

## 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.

### 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.

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### 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

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Formaldehyde

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

ACGIH Ceiling Threshold Limit:

= 0.3 ppm Ceiling

ACGIH - Sensitizer Designation

Sensitizer

Australia STEL

= 2 ppm STEL

= 2.5 mg/m<sup>3</sup> STEL

Australia TWA

= 1 ppm TWA

= 1.2 mg/m<sup>3</sup> TWA

### Merthiolate (as mercury)

OSHA - Final PELs - TWAs:

= 0.01 mg/m<sup>3</sup> TWA

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

Skin - potential significant contribution to overall exposure by the cutaneous route

Australia STEL

= 0.03 mg/m<sup>3</sup> STEL

Australia TWA

= 0.01 mg/m<sup>3</sup> 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

Skin:

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

Respiratory protection:

In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Liquid solution in multiple-dose vials	<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		

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

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

**Polymerization:** Will not occur

### 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. The information included in this section describes the potential hazards of the individual ingredients.

#### 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

##### **Inhalation Acute Toxicity**

Not determined for this mixture. However, irritation may occur based on effects of individual components.

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

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

Eye Irritation Rabbit Mild

##### **Gentamicin**

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Eye Irritation    Rabbit    Non-irritating

### Formaldehyde

Eye Irritation    Rabbit    Severe

Skin Irritation    Rabbit    Moderate Severe

**Skin Irritation / Sensitization**      This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

### 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

**Subchronic Effects**      Rats exposed to 15 ppm formaldehyde vapor for six hours/day for up to nine days showed an acute cell degeneration, necrosis and inflammation in the nasal cavities. Inhalation exposure to formaldehyde for up to 90 days produced interstitial inflammation in the lungs of dogs, rats, monkeys, rabbits and guinea pigs.

**Chronic Effects/Carcinogenicity**      In rats, several inhalation studies have shown that formaldehyde induces squamous-cell carcinomas and necrosis of the nasal cavity. Formaldehyde also showed cocarcinogenic effects when inhaled, ingested, or applied to the skin of rodents.

### 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

**Reproductive Effects**      Not considered to be a reproductive hazard.

**Teratogenicity**      Formaldehyde has been tested by inhalation, oral, and dermal routes and has not been shown to be teratogenic in animals.

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

#### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames)    Bacteria    Positive

*In Vitro* Chromosome Aberration    Rodent    Positive

*In Vitro* Sister Chromatid Exchange    Rodent    Positive

*In Vivo* Chromosome Aberration    Not specified    Positive

**Mutagenicity**      Formaldehyde has been reported to be active in many short-term tests, both in vitro and in vivo.

### 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:**      Contains formaldehyde: potential cancer hazard. See below

#### Formaldehyde

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IARC:	Group 1
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.

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Observe all local and national regulations when disposing of this material. 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).

Formaldehyde

RCRA - U Series Wastes

waste number U122

### 14. TRANSPORT INFORMATION

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

### 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.  
S37 - Wear suitable gloves.

**OSHA Label:**

WARNING

Contains formaldehyde: potential cancer hazard.

May cause sensitization of the skin and respiratory system.

May cause eye, skin and respiratory tract irritation.

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### Canada - WHMIS: Classifications

#### WHMIS hazard class:

Class D, Division 2, Subdivision A



#### Gentamicin

California Proposition 65

Australia (AICS):

Standard for the Uniform Scheduling  
for Drugs and Poisons:

EU EINECS List

Aminoglycosides- developmental

Present

Schedule 4

215-765-8

#### Formaldehyde

CERCLA/SARA 313 Emission reporting

CERCLA/SARA Hazardous Substances  
and their Reportable Quantities:

CERCLA/SARA - Section 302 Extremely Hazardous  
TPQs

CERCLA/SARA - Section 302 Extremely Hazardous  
Substances EPCRA RQs

California Proposition 65

OSHA - Specifically Regulated Chemicals

= 0.1 % de minimis concentration

= 100 lb final RQ

= 45.4 kg final RQ

= 500 lb TPQ

= 100 lb EPCRA RQ

carcinogen, initial date 1/1/88 (gas)

= 0.5 ppm Action Level

= 0.75 ppm TWA

= 2 ppm STEL Irritant and potential cancer hazard - see 29 CFR  
1910.1048

Present

Present

Schedule 2

Schedule 6

200-001-8

#### Merthiolate (as mercury)

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

= 1.0 % Supplier notification limit

Developmental

Present

Present

200-210-4

#### Water, purified

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present

Present

231-791-2

### 16. OTHER INFORMATION

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**Reasons for Revision:**

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.  
Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls /  
Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section  
11 - Toxicology Information. Updated Section 15 - Regulatory Information.

**Prepared by:**

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**