



# MATERIAL SAFETY DATA SHEET

Revision date: 21-May-2012

Version: 1.0

Page 1 of 8

## 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  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
International CHEMTREC (24 hours): +1-703-527-3887

### Material Name: EQUIP West Nile Vaccine

Trade Name:	EQUIP WNV
Synonyms:	DUVAXYN WNV
Chemical Family:	Not determined
Intended Use:	Veterinary Vaccine

## 2. HAZARDS IDENTIFICATION

**Appearance:** Liquid emulsion

**Statement of Hazard:** Contains formaldehyde: potential cancer hazard

**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.

**EU Classification**

**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.

## MATERIAL SAFETY DATA SHEET

Material Name: EQUIP West Nile Vaccine  
Revision date: 21-May-2012

Page 2 of 8  
Version: 1.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Formaldehyde	50-00-0	200-001-8	C;R34 Carc. Cat.3;R40 R43 T;R23/24/25	<0.1
Gentamicin sulfate	1405-41-0	215-778-9	Repr.Cat.1;R61 Xi;R43	<0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
ETHYLENE OXIDE/PROPYLENE OXIDE COPOLYMER	9003-11-6	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Squalene	111-02-4	203-826-1	Not Listed	*
West Nile Virus (strain VM-2)	Not Assigned	Not Listed	Not Listed	*

#### Additional Information:

\* Proprietary

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

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire Fighting Procedures:</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

## MATERIAL SAFETY DATA SHEET

Material Name: EQUIP West Nile Vaccine  
Revision date: 21-May-2012

Page 3 of 8  
Version: 1.0

### 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.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	Minimize generating airborne mists and vapors. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
<b>Storage Conditions:</b>	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Sensitizer
Australia STEL	2 ppm
	2.5 mg/m <sup>3</sup>
Australia TWA	1 ppm
	1.2 mg/m <sup>3</sup>
Austria OEL - MAKs	0.5 ppm
	0.6 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.5 mg/m <sup>3</sup>
Estonia OEL - TWA	0.5 ppm
	0.6 mg/m <sup>3</sup>
Finland OEL - TWA	0.3 ppm
	0.37 mg/m <sup>3</sup>
France OEL - TWA	0.5 ppm
Germany (DFG) - MAK	0.3 ppm
	0.37 mg/m <sup>3</sup>
Greece OEL - TWA	2 ppm
	2.5 mg/m <sup>3</sup>
Hungary OEL - TWA	0.6 mg/m <sup>3</sup>
Ireland OEL - TWAs	2 ppm
	2.5 mg/m <sup>3</sup>
Japan - OELs - Ceilings	0.2 ppm
	0.24 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>

## MATERIAL SAFETY DATA SHEET

Material Name: EQUIP West Nile Vaccine  
Revision date: 21-May-2012

Page 4 of 8  
Version: 1.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA	0.5 ppm 0.6 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.15 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	0.75 ppm
OSHA - Specifically Regulated Chemicals	2 ppm 0.5 ppm 0.75 ppm
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Romania OEL - TWA	1 ppm 1.20 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.3 ppm 0.37 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.5 ppm 0.62 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.5 ppm 0.6 mg/m <sup>3</sup>

<b>Engineering Controls:</b>	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. Keep airborne contamination levels below the exposure limits listed above in this section.
<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>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Liquid Emulsion	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Flash Point (Liquid) (°C):</b>	Non-flammable		
<b>Polymerization:</b>	Will not occur		

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<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: EQUIP West Nile Vaccine  
Revision date: 21-May-2012

Page 5 of 8  
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 information included in this section describes the potential hazards of the individual ingredients.

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

##### **Formaldehyde**

Rat Oral LD50 800 mg/kg

##### **Polysorbate 80**

Rat Oral LD50 25 g/kg

##### **Gentamicin sulfate**

Rat Oral LD50 > 5000 mg/kg

Rat Para-periosteal LD50 96 mg/kg

Rat Intramuscular LD50 384 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

##### **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

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **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

##### **Gentamicin sulfate**

Embryo / Fetal Development Rat Intraperitoneal 375 mg/kg/day LOAEL Developmental toxicity

Prenatal & Postnatal Development Rat Subcutaneous 660 mg/kg/day LOAEL Developmental toxicity

Prenatal & Postnatal Development Rat Subcutaneous 660 mg/kg/day LOAEL Neonatal toxicity

#### 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

## MATERIAL SAFETY DATA SHEET

Material Name: EQUIP West Nile Vaccine  
Revision date: 21-May-2012

Page 6 of 8  
Version: 1.0

### 11. TOXICOLOGICAL INFORMATION

*In Vivo* Chromosome Aberration    Not specified    Positive

#### Gentamicin sulfate

DNA Binding Assay    *E. coli*    Negative

#### 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:

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

##### Formaldehyde

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

### 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

**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).

##### Formaldehyde

RCRA - U Series Wastes    Listed

### 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.

## MATERIAL SAFETY DATA SHEET

Material Name: EQUIP West Nile Vaccine  
Revision date: 21-May-2012

Page 7 of 8  
Version: 1.0

### 15. REGULATORY INFORMATION

EU Indication of danger: Not classified

#### OSHA Label:

Contains formaldehyde: potential cancer hazard

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

None required

#### ETHYLENE OXIDE/PROPYLENE OXIDE COPOLYMER

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

#### Formaldehyde

CERCLA/SARA 313 Emission reporting	0.1 %
CERCLA/SARA Hazardous Substances	100 lb
and their Reportable Quantities:	45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	100 lb
California Proposition 65	carcinogen initial date 1/1/88
OSHA - Specifically Regulated Chemicals	2 ppm
	0.5 ppm
	0.75 ppm
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

#### Gentamicin sulfate

California Proposition 65	Aminoglycosides- developmental
Australia (AICS):	Present
EU EINECS/ELINCS List	215-778-9

#### Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

## MATERIAL SAFETY DATA SHEET

Material Name: EQUIP West Nile Vaccine  
Revision date: 21-May-2012

Page 8 of 8  
Version: 1.0

### 15. REGULATORY INFORMATION

#### Squalene

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-826-1

### 16. OTHER INFORMATION

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

R34 - Causes burns.  
R40 - Limited evidence of a carcinogenic effect  
R43 - May cause sensitization by skin contact.  
R61 - May cause harm to the unborn child.  
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

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

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

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**End of Safety Data Sheet**