

# SAFETY DATA SHEET



Revision date: 24-Feb-2014

Version: 2.0

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

### Product Identifier

**Material Name:** Arvac

**Trade Name:**

Arvac

**Synonyms:**

Equine Arteritis Vaccine (modified live virus)

**Chemical Family:**

Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary Vaccine

### Details of the Supplier of the Safety Data Sheet

**Zoetis Inc.**

100 Campus Drive, P.O. Box 651

Florham Park, New Jersey 07932 (USA)

Rocky Mountain Poison Control Center Phone: 1-866-531-8896

Product Support/Technical Services Phone: 1-800-366-5288

**Zoetis Belgium S.A.**

Mercuriusstraat 20

1930 Zaventem

Belgium

**Emergency telephone number:**

CHEMTREC (24 hours): 1-800-424-9300

**Contact E-Mail:** VMIPRecords@zoetis.com

**Emergency telephone number:**

International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

**Appearance:** Pale Yellow to Reddish-white Powder

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Signal Word:** Not Classified

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

### Other Hazards

**Short Term:** Not expected to cause skin irritation Not expected to cause eye irritation. In the event of accidental injection, an allergic reaction may occur.

### Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Amphotericin B	1397-89-3	215-742-2	Not Listed	Not Listed	##
Thimerosal	54-64-8	200-210-4	T+; R26/27/28; R33 N; R50/53	Acute Tox. 2 (H300) Acute Tox. 1 (H310) STOT RE 2 (H373) Acute Tox. 2 (H330) Acute Aquatic 1 (H400) Chronic Aquatic 1 (H410)	##
Neomycin sulfate	1405-10-3	Not Listed	Not Listed	Not Listed	##
Polymyxin B	1404-26-8	215-768-4	Xn;R22 Xn;R42/43	Acute Tox. 4 (H302) Skin Sens. 1 (H317) Resp Sens. 1 (H334)	##
Formaldehyde	50-00-0	200-001-8	T; R23/24/25 C; R34 Carc.Cat.3; R40 R43	Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Carc. 1A (H350) Acute Tox. 3 (H331)	##

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Equine Arteritis Virus, modified live virus	Not Assigned	Not Listed	Not Listed	Not Listed	*
Sterile Diluent	Not assigned	Not Listed	Not Listed	Not Listed	> 50

**Additional Information:**

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

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:**

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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**Ingestion:** 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.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of** No data available

**Exposure:**

**Medical Conditions** None known

**Aggravated by Exposure:**

### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

## 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion** Formation of toxic gases is possible during heating or fire.

**Products:**

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

### Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

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

### Environmental Precautions

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

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**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

### Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Avoid breathing dust. Avoid contact with eyes, skin and clothing. Minimize dust generation and accumulation. Keep away from heat, sparks, and flame. Avoid accidental injection.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Specific end use(s):** No data available

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

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

**Neomycin sulfate**

Zoetis OEL TWA 8-hr 100µg/m<sup>3</sup>, Sensitizer

**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> no irritation should occur during mixed exposure
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>
Lithuania OEL - TWA	0.5 ppm
	0.6 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.15 mg/m <sup>3</sup>
Vietnam OEL - TWAs	0.5 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	0.3 ppm
	0.37 mg/m <sup>3</sup>
Switzerland OEL - TWAs	0.3 ppm
	0.37 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Polymyxin B

##### Zoetis OEB

OEB 2 - Sensitizer (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, provide additional precautions to protect from skin contact)

#### Exposure Controls

##### Engineering Controls:

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.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

##### Hands:

Wear impervious gloves if skin contact is possible.

##### Eyes:

Safety glasses or goggles

##### Skin:

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

##### 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. 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Powder	<b>Color:</b>	Pale Yellow to Reddish-white
<b>Odor:</b>	Odorless	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	Soluble		
<b>pH:</b>	6 - 8		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		No data available	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

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### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of the individual ingredients. Toxicological properties of the formulation have not been investigated. The antigens included in this product are non-infectious. All have been prepared from modified or inactivated preparations of microorganisms.

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

##### Thimerosal

Rat Oral LD50 75 mg/kg  
Mouse Oral LD50 91 mg/kg  
Rat Subcutaneous LD50 98mg/kg

##### Polymyxin B

Mouse Oral LD50 790 mg/kg  
Mouse Para-periosteal LD50 3980ug/kg  
Rat Subcutaneous LD50 50mg/kg

##### Amphotericin B

Rat Oral LD50 > 5000 mg/kg  
Rat Para-periosteal LD50 1.6mg/kg  
Rat Intraperitoneal LD50 > 5000mg/kg  
Mouse Intravenous LD50 1.2mg/kg  
Mouse Intraperitoneal LD50 27.7mg/kg

##### Formaldehyde

Rat Oral LD50 800 mg/kg

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

##### Thimerosal

Eye Irritation Rabbit Mild

##### Formaldehyde

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate Severe  
Skin Sensitization Positive

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

##### Amphotericin B

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### 11. TOXICOLOGICAL INFORMATION

30 Day(s)	Dog	Intravenous	37 mg/kg/day	LOAEL	Kidney
2 Month(s)	Dog	Intravenous	16.5 mg/kg/day	LOAEL	Kidney
13 Week(s)	Rat	Oral	2 mg/kg/day	NOAEL	Male reproductive system, Female reproductive system
13 Week(s)	Dog	Oral	1.6 mg/kg/day	NOAEL	Male reproductive system, Female reproductive system

#### 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
90 Day(s)	Rat	Inhalation	15 ppm	LOAEL Respiratory system

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

##### Amphotericin B

Embryo / Fetal Development	Rat	Oral	7.5 mg/kg/day	NOAEL	Not teratogenic, Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral	10 mg/kg/day	NOAEL	Not Teratogenic, Fetotoxicity

##### 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)

##### Polymyxin B

*In Vitro* Negative  
*In Vivo* Negative

##### Amphotericin B

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative

##### Formaldehyde

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	Bacteria	Positive
<i>In Vitro</i> Chromosome Aberration	Rodent	Positive
<i>In Vitro</i> Sister Chromatid Exchange	Rodent	Positive
<i>In Vivo</i> Chromosome Aberration	Not specified	Positive

##### 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:	Known Human Carcinogen
OSHA:	Listed





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## 15. REGULATORY INFORMATION

### Amphotericin B

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	215-742-2

### Equine Arteritis Virus, modified live virus

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### Sterile Diluent

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### Thimerosal

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-210-4

### Neomycin sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity initial date 10/1/92 internal use
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

### Polymyxin B

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	215-768-4

### Formaldehyde

CERCLA/SARA 313 Emission reporting	0.1 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen initial date 1/1/88 gas
	2 ppm
	0.5 ppm
	0.75 ppm
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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### 15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 6
	200-001-8

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H300 - Fatal if swallowed  
H301 - Toxic if swallowed  
H302 - Harmful if swallowed  
H310 - Fatal in contact with skin  
H314 - Causes severe skin burns and eye damage  
H317 - May cause an allergic skin reaction  
H330 - Fatal if inhaled  
H331 - Toxic if inhaled  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H350 - May cause cancer  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects

Carcinogenic: Category 3  
T+ - Very toxic  
T - Toxic  
C - Corrosive  
Xn - Harmful  
N - Dangerous for the environment

R22 - Harmful if swallowed.  
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.  
R42/43 - May cause sensitization by inhalation and skin contact.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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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.

**End of Safety Data Sheet**