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

**Product Identifier** 

Material Name: EQUINE RHINOPNEUMONITIS VACCINE, KILLED VIRUS

Trade Name: Pneumabort K+1b

Compound Number: 1525.21 Chemical Family: Not determined

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

Intended Use: Veterinary Vaccine
Restrictions on Use: Not for human use

**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: VMIPSrecords@zoetis.com

Emergency telephone number:

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

# 2. HAZARDS IDENTIFICATION

Appearance: White to Pale Pink suspension

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:** 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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing

products may cause severe vasospasm following accidental injection.

Australian Hazard Classification

(NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

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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.

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### **Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Mineral oil, white	8042-47-5	232-455-8	Not Listed	Not Listed	1
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)	<0.1
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)	<0.1
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)	<0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Amphotericin B	1397-89-3	215-742-2	Not Listed	Not Listed	*
Inactivated Equine Herpes virus type 1	Not Assigned	Not Listed	Not Listed	Not Listed	*
Polysorbate 60	9005-67-8	Not Listed	Not Listed	Not Listed	*
Sorbitan monostearate	1338-41-6	215-664-9	Not Listed	Not Listed	*
Equine Herpesvirus type 1b	Not Assigned	Not Listed	Not Listed	Not Listed	*
Sodium Chloride Solution	Not Assigned	Not Listed	Not Listed	Not Listed	*
Neomycin Free Base	1404-04-2	215-766-3	Not Listed	Not Listed	*

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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<sup>\*</sup> Proprietary

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For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

# 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.

**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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards

**Exposure:** Identification and/or Section 11 - Toxicological Information.

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:** 

Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 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 / Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill

**Collecting:** area thoroughly.

Additional Consideration for

Large Spills: situations immediately. Clean up operations should only be undertaken by trained personnel.

Non-essential personnel should be evacuated from affected area. Report emergency

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# 7. HANDLING AND STORAGE

#### **Precautions for Safe Handling**

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.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy

metals.

Specific end use(s): No data available

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### **Control Parameters**

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

Mineral oil, white

ACGIH Threshold Limit Value (TWA) 5 mg/m<sup>3</sup>

ACGIH Threshold Limit Value (STEL) 10 mg/m³ (oil mist)

Sorbitan monostearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Formaldehyde

ACGIH Ceiling Threshold Limit:

ACGIH - Sensitizer Designation

Australia STEL

2 ppm
2.5 mg/m³

Australia TWA

1 ppm
1.2 mg/m³

Austria OEL - MAKs

0.5 ppm

0.6 mg/m³

Bulgaria OEL - TWA

1.0 mg/m³

Czech Republic OEL - TWA

0.5 mg/m³

Estonia OEL - TWA

0.5 ppm

 $\begin{array}{c} 0.6 \text{ mg/m}^3 \\ \hline \text{Finland OEL - TWA} \\ 0.3 \text{ ppm} \\ 0.37 \text{ mg/m}^3 \\ \end{array}$ 

France OEL - TWA 0.5 ppm Germany (DFG) - MAK 0.3 ppm

0.37 mg/m³ no irritation should occur during mixed exposure

 $\begin{tabular}{lll} \textbf{Greece OEL - TWA} & 2 \text{ ppm} \\ 2.5 \text{ mg/m}^3 \\ \textbf{Hungary OEL - TWA} & 0.6 \text{ mg/m}^3 \\ \textbf{Ireland OEL - TWAs} & 2 \text{ ppm} \\ \end{tabular}$ 

Japan - OELs - Ceilings 2.5 mg/m³ 0.2 ppm

0.24 mg/m<sup>3</sup> **Latvia OEL - TWA**0.5 mg/m<sup>3</sup>

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# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA 0.5 ppm 0.6 mg/m<sup>3</sup> **Netherlands OEL - TWA**  $0.15 \text{ mg/m}^3$ 0.5 mg/m<sup>3</sup> **Vietnam OEL - TWAs 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>

0.3 ppm Slovakia OEL - TWA 0.37 mg/m<sup>3</sup> 0.5 ppm Slovenia OEL - TWA

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>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Polymyxin B

OEB 2 - Sensitizer (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, provide **Zoetis OEB** 

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. Keep air contamination levels below the exposure limits or within the OEB range listed above in this

section.

**Personal Protective** 

Refer to applicable national standards and regulations in the selection and use of personal **Equipment:** 

protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk

processing operations.

Wear safety glasses or goggles if eye contact is possible. Eves:

Impervious protective clothing is recommended if skin contact with drug product is possible and Skin:

for bulk processing operations.

Respiratory protection: Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection,

with appropriate protection factors, should be used to minimize exposure.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Suspension Color: White to Pale pink Odor: No data available. **Odor Threshold:** No data available.

Molecular Formula: Mixture **Molecular Weight:** Mixture

**Solvent Solubility:** No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility:

pH:

No data available

No data available.

Melting/Freezing Point (°C):

No data available

No data available

No data available

No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

**Decomposition Temperature (°C):** No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

No data available

Flammablity:

Autoignition Temperature (Solid) (°C):

Flammability (Solids):

Flash Point (Liquid) (°C):

Upper Explosive Limits (Liquid) (% by Vol.):

Lower Explosive Limits (Liquid) (% by Vol.):

Polymerization:

No data available
No data available
Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions** 

Oxidizing Properties: None

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy

metals.

**Hazardous Decomposition** 

**Products:** 

No data available

# 11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

**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)

**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

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# 11. TOXICOLOGICAL INFORMATION

Rat Subcutaneous LD50 50mg/kg

Polysorbate 60

Rat Oral LD50 64,000 mg/kg

Amphotericin B

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

Mineral oil, white

Oral LD50 > 5000 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)

**Thimerosal** 

Eye Irritation Rabbit Mild

Mineral oil, white

Skin Irritation Rabbit Slight Eye Irritation Rabbit Slight

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)

Amphotericin B

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

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

**Amphotericin B** 

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

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

Polymyxin B

In Vitro Negative In Vivo Negative

Amphotericin B

**Bacterial Mutagenicity (Ames)** Salmonella , E. coli Negative

In Vivo Micronucleus Mouse Negative

In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

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# 11. TOXICOLOGICAL INFORMATION

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.

### 12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. This product

contains trace quantities of mercury, releases to the environment should be avoided.

**Toxicity:** No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

# 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.

# 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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# 15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Mineral oil, white

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Listed

Not Eisted

Not

**Amphotericin B** 

CERCLA/SARA 313 Emission reporting

California Proposition 65

Australia (AICS):

Standard for the Uniform Scheduling

Not Listed

Not Listed

Present

Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 215-742-2

Inactivated Equine Herpes virus type 1

CERCLA/SARA 313 Emission reporting

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

Polysorbate 60

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Sorbitan monostearate

**Equine Herpesvirus type 1b** 

CERCLA/SARA 313 Emission reporting Not Listed

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15. REGULATORY INFORMATION

California Proposition 65 Not Listed
EU EINECS/ELINCS List Not Listed

**Sodium Chloride Solution** 

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed

Not Listed

**Thimerosal** 

CERCLA/SARA 313 Emission reporting

California Proposition 65

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

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not

Polymyxin B

CERCLA/SARA 313 Emission reporting

California Proposition 65

EU EINECS/ELINCS List

Not Listed
215-768-4

**Neomycin Free Base** 

CERCLA/SARA 313 Emission reportingNot ListedCalifornia Proposition 65Not ListedStandard for the Uniform SchedulingSchedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List 215-766-3

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 500 lb

**TPQs** 

CERCLA/SARA - Section 302 Extremely Hazardous

**Substances EPCRA RQs** 

California Proposition 65 carcinogen initial date 1/1/88 gas

OSHA - Specifically Regulated Chemicals 2 ppm 0.5 ppm 0.75 ppm

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

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

Present
Schedule 2
Schedule 6
200-001-8

# **16. OTHER INFORMATION**

100 lb

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

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Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Acute toxicity, dermal-Cat.1; H310 - Fatal in contact with skin

Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Carcinogenicity-Cat.1A; H350 - May cause cancer

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

Carcinogenic: Category 3

C - Corrosive
T+ - Very toxic
T - Toxic

N - Dangerous for the environment

Xn - Harmful

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 7 - Handling and Storage. Updated Section 8 - Exposure

Controls / Personal Protection.

Prepared by: Toxicology and Hazard Communication

Zoetis Global Risk Management

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**