SAFETY DATA SHEETS

This SDS packet was issued with item:

078036942

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078036934 078413659

SAFETY DATA SHEET

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

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

Contact E-Mail: VMIPSrecords@zoetis.com

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.

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

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

Medical Conditions Aggravated by Exposure: None known

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 Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: 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 / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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

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^3
ACGIH Threshold Limit Value (STEL)	10 mg/m^3 (oil mist)

Sorbitan monostearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3

Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Sensitizer
Australia STEL	2 ppm 2.5 mg/m^3
Australia TWA	1 ppm 1.2 mg/m^3
Austria OEL - MAKs	0.5 ppm 0.6 mg/m^3
Bulgaria OEL - TWA	1.0 mg/m^3
Czech Republic OEL - TWA	0.5 mg/m^3
Estonia OEL - TWA	0.5 ppm 0.6 mg/m^3
Finland OEL - TWA	0.3 ppm 0.37 mg/m^3
France OEL - TWA	0.5 ppm
Germany (DFG) - MAK	0.3 ppm 0.37 mg/m^3 no irritation should occur during mixed exposure
Greece OEL - TWA	2 ppm 2.5 mg/m^3
Hungary OEL - TWA	0.6 mg/m^3
Ireland OEL - TWAs	2 ppm 2.5 mg/m^3
Japan - OELs - Ceilings	0.2 ppm 0.24 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA	0.5 ppm 0.6 mg/m^3
Netherlands OEL - TWA	0.15 mg/m^3
Vietnam OEL - TWAs	0.5 mg/m^3
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^3
Romania OEL - TWA	1 ppm 1.20 mg/m^3
Slovakia OEL - TWA	0.3 ppm 0.37 mg/m^3
Slovenia OEL - TWA	0.5 ppm 0.62 mg/m^3
Sweden OEL - TWAs	0.3 ppm 0.37 mg/m^3
Switzerland OEL -TWAs	0.3 ppm 0.37 mg/m^3

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

Zoetis OEB OEB 2 - Sensitizer (control exposure to the range of 100ug/m^3 to < 1000ug/m^3, 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. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

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

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

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): Non-flammable
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: 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

11. TOXICOLOGICAL INFORMATION

Rat Subcutaneous LD50 50mg/kg

Polysorbate 60
Rat Oral LD50 64,000 mg/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

Mineral oil, white
Rat 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
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

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

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

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

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	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-455-8

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

Inactivated Equine Herpes virus type 1

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

Polysorbate 60

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	Not Listed

Sorbitan monostearate

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	215-664-9

Equine Herpesvirus type 1b

CERCLA/SARA 313 Emission reporting	Not Listed

15. REGULATORY INFORMATION

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

Sodium Chloride Solution

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

Polymyxin B

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

Neomycin Free Base

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	215-766-3

Formaldehyde

CERCLA/SARA 313 Emission reporting	0.1 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb 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 gas
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

16. OTHER INFORMATION

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

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