# SAFETY DATA SHEET



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

**Product Identifier**

**Material Name: Pro Vac® 4 ACL™**

**Trade Name:** Pro Vac®
**Synonyms:** Newcastle Disease virus, Infectious Bronchitis Disease virus, Infectious Bursal Disease virus, Reovirus, inactivated vaccine
**Chemical Family:** Mixture

**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:** Liquid

**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 | % |
|---|---|---|---|---|---|
| Gentamicin | 1403-66-3 | 215-765-8 | Not Listed | Not Listed | ## |
| Amphotericin B | 1397-89-3 | 215-742-2 | Not Listed | Not Listed | ## |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---|---|---|---|---|---|
| Inactivated IB Virus, strain Massachusetts M41 | Not assigned | Not Listed | Not Listed | Not Listed | * |
| Inactivated REO Virus, strain S1133 | Not assigned | Not Listed | Not Listed | Not Listed | * |
| Inactivated ND Virus, strain Ulster | Not assigned | Not Listed | Not Listed | Not Listed | * |
| Inactivated IBD Virus, strain Winterfield 2512 | Not assigned | Not Listed | Not Listed | Not Listed | * |
| Adjuvant - oil emulsion | Proprietary | Not Listed | Not Listed | Not Listed | * |

**Additional Information:** ## Trace
* 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:** No data available

**Medical Conditions Aggravated by Exposure:** None known

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

**Notes to Physician:** Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.

## 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 the spill or leak. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal.

**Additional Consideration for Large Spills:** Contain the source of the spill or leak if it is safe to do so. Prevent discharge to drains. Dike, pump, or use non-combustible material to absorb spill; then place in a labeled container for disposal. Close container and move it to a secure holding area.

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

Avoid accidental injection. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment. 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.

**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.**

**Gentamicin**

**Bulgaria OEL - TWA** 0.1 mg/m$^3$

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

**Gentamicin**

**Zoetis OEB** OEB 2 (control exposure to the range of 100ug/$m^3$ to < 1000ug/$m^3$)

**Exposure Controls**

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**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:** 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:** 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

| | | | |
|---|---|---|---|
| **Physical State:** | Opaque liquid | **Color:** | Pale yellow to Reddish white |
| **Odor:** | Odorless | **Odor Threshold:** | No data available. |
| **Molecular Formula:** | Mixture | **Molecular Weight:** | Mixture |

**Solvent Solubility:** No data available
**Water Solubility:** Miscible:
**pH:** 6 - 8
**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:** No data available
**Conditions to Avoid:** High temperatures
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
**Hazardous Decomposition Products:** Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

# 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**
**General Information:** Toxicological properties of the formulation have not been fully investigated. The following information is available for the individual ingredients. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.

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

**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
**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)**

**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

**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

**Amphotericin B**
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
*In Vivo* Micronucleus Mouse Negative
*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties of the formulation have not been investigated.

**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.

## 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**

**Canada - WHMIS: Classifications**
**WHMIS hazard class:**
None required
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.

**Inactivated IB Virus, strain Massachusetts M41**

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

## 15. REGULATORY INFORMATION

**Inactivated REO Virus, strain S1133**

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

**Inactivated ND Virus, strain Ulster**

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

**Inactivated IBD Virus, strain Winterfield 2512**

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

**Gentamicin**

| | |
|---|---|
| **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** | 215-765-8 |

**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 |

**Adjuvant - oil emulsion**

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

## 16. OTHER INFORMATION

**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.

**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**