

SAFETY DATA SHEET



Revision date: 05-Nov-2014

Version: 2.5

Page 1 of 7

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

Product Identifier

Material Name: AE-Vac

Trade Name:

Poulvac®

Synonyms:

Avian Encephalomyelitis, Live Virus; Poulvac AE Vac; Poulvac AE

Chemical Family:

Mixture

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

Intended Use: Poultry 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: Lyophilized 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: May cause eye and skin irritation. 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.

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

ZT00047

AE-LIVE

#013031

11/5/15

PAGE 1 of 7

SAFETY DATA SHEET

Material Name: AE-Vac
Revision date: 05-Nov-2014

Page 2 of 7
Version: 2.5

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	##

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Avian Encephalomyelitis, Live Virus	Not assigned	Not Listed	Not Listed	Not Listed	*
Excipients	Proprietary	Not Listed	Not Listed	Not Listed	*

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

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get 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

SAFETY DATA SHEET

Material Name: AE-Vac
Revision date: 05-Nov-2014

Page 3 of 7
Version: 2.5

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

Avoid dust formation. 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 proper personal protective equipment as specified in Section 8. Use with adequate ventilation. Avoid generating airborne dust. Avoid inhalation and contact with skin, eye, and clothing. Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Veterinary Vaccine

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/m³

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/m³ to < 1000ug/m³)

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.

SAFETY DATA SHEET

Material Name: AE-Vac
Revision date: 05-Nov-2014

Page 4 of 7
Version: 2.5

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:	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:	Lyophilized powder	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:	Soluble		
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		
Flammability:			
Autoignition Temperature (Solid) (°C):		No data available	
Flammability (Solids):		No data available	
Flash Point (Liquid) (°C):		No data available	
Upper Explosive Limits (Liquid) (% by Vol.):		No data available	
Lower Explosive Limits (Liquid) (% by Vol.):		No data available	

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:	Extremes of temperature and direct sunlight.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

SAFETY DATA SHEET

Material Name: AE-Vac
Revision date: 05-Nov-2014

Page 5 of 7
Version: 2.5

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

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

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

Gentamicin

Rat Oral LD50 6600 mg/kg
Rat Subcutaneous LD50 710mg/kg
Mouse IM LD50 167 mg/kg
Rat IM LD50 463 mg/kg

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

Gentamicin

Eye Irritation Rabbit Non-irritating

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Gentamicin

Embryo / Fetal Development Rat Intramuscular 75 mg/kg/day LOAEL Developmental toxicity

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. 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

SAFETY DATA SHEET

Material Name: AE-Vac
Revision date: 05-Nov-2014

Page 6 of 7
Version: 2.5

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:

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.

Avian Encephalomyelitis, Live Virus

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

developmental toxicity initial date 10/1/92

Australia (AICS):

Present

Standard for the Uniform Scheduling

Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List

215-765-8

Excipients

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

SAFETY DATA SHEET

Material Name: AE-Vac
Revision date: 05-Nov-2014

Page 7 of 7
Version: 2.5

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. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties.

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