

SAFETY DATA SHEET



Revision date: 14-Oct-2013

Version: 2.0

Page 1 of 7

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

Product Identifier

Material Name: Canine Influenza

Trade Name: Vanguard CIV
Synonyms: Canine influenza virus H3N8, killed virus
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: Clear liquid
Classification of the Substance or Mixture
GHS - Classification Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements

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

Other Hazards

Short Term: May cause allergic skin reaction (based on components) . 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.

Long Term: Repeated exposure to dust or mist may produce allergic reactions.
Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

SAFETY DATA SHEET

Material Name: Canine Influenza
Revision date: 14-Oct-2013

Page 2 of 7
Version: 2.0

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	<0.1%

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Canine influenza virus	Not assigned	Not Listed	Not Listed	Not Listed	*
Aluminum hydroxide gel	21645-51-2	244-492-7	Not Listed	Not Listed	*

Additional Information: * 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: Remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical assistance if skin reaction occurs, which may be immediate or delayed.

Ingestion: In the event of swallowing this material, seek medical advice or consult the emergency contact listed in section 1.

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

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 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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

SAFETY DATA SHEET

Material Name: Canine Influenza
Revision date: 14-Oct-2013

Page 3 of 7
Version: 2.0

Hazardous Combustion Products: Toxic or corrosive gases are expected in fires involving this mixture.

Fire / Explosion Hazards: Not applicable

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 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

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.

Aluminum hydroxide gel

ACGIH Threshold Limit Value (TWA)	1 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Germany (DFG) - MAK	4 mg/m ³
	1.5 mg/m ³
Latvia OEL - TWA	6 mg/m ³
Lithuania OEL - TWA	6 mg/m ³
Poland OEL - TWA	2.5 mg/m ³
	1.2 mg/m ³
Slovakia OEL - TWA	1.5 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³

SAFETY DATA SHEET

Material Name: Canine Influenza
Revision date: 14-Oct-2013

Page 4 of 7
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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:

None required under normal conditions of use. 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:

Liquid

Color:

Clear

Odor:

No data available.

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

Solubility:

Soluble: Water (based on components)

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

Flammability:

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

SAFETY DATA SHEET

Material Name: Canine Influenza
Revision date: 14-Oct-2013

Page 5 of 7
Version: 2.0

Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Not expected to occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
Hazardous Decomposition Products: None expected under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Aluminum hydroxide gel

Rat Para-periosteal LD50 150 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.

SAFETY DATA SHEET

Material Name: Canine Influenza
Revision date: 14-Oct-2013

Page 6 of 7
Version: 2.0

12. ECOLOGICAL INFORMATION

Environmental Overview:	The environmental characteristics of this mixture have not been fully evaluated. 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.
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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.

Canine influenza virus

CERCLA/SARA 313 Emission reporting
California Proposition 65

Not Listed
Not Listed

SAFETY DATA SHEET

Material Name: Canine Influenza
Revision date: 14-Oct-2013

Page 7 of 7
Version: 2.0

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed
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Aluminum hydroxide gel

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	244-492-7

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

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.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material 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