

SAFETY DATA SHEETS

This SDS packet was issued with item:

078936359

N/A

SAFETY DATA SHEET



Revision date: 04-Mar-2015

Version: 2.5

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

Product Identifier

Material Name: Felocell FeLV (Feline Leukemia Vaccine, Killed Virus)

Trade Name: Felocell FeLV, Versifel FeLV
Synonyms: Feline Leukemia Vaccine, 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 and Drug 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: Light orange to pink liquid (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

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Short Term:

In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously. Non-Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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 | % |
|------------------|------------|-----------------------|-------------------|--------------------|----|
| Polyacrylic acid | 9003-01-4 | Not Listed | Not Listed | Not Listed | ## |
| Quil-A saponin | 66594-14-7 | Not Listed | Not Listed | Not Listed | ## |
| Gentamicin | 1403-66-3 | 215-765-8 | Not Listed | Not Listed | ## |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--------------------------------------|--------------|-----------------------|-------------------|--------------------|---|
| Dimethyldioctadecyl ammonium bromide | 3700-67-2 | 223-037-6 | Not Listed | Not Listed | * |
| Cholesterol | 57-88-5 | 200-353-2 | Not Listed | Not Listed | * |
| Feline leukemia virus | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |

Additional Information:

Trace

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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

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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

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin and clothing. Avoid breathing dust, vapor or mist. Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store under refrigeration in closed container. Do not freeze.

Storage Temperature: 2-7°C. Do not freeze.

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

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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Polyacrylic acid

Switzerland OEL -TWAs 0.05 mg/m³

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

Wear impervious gloves if skin contact is possible.

Eyes:

Safety glasses or goggles

Skin:

Wear protective clothing when working with large quantities.

Respiratory protection:

None required under normal conditions of use. 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: Liquid suspension

Odor: No data available.

Molecular Formula: Mixture

Color: Light orange to pink

Odor Threshold: No data available.

Molecular Weight: Mixture

Solvent Solubility: No data available

Water Solubility: No data available

pH: 7.0

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

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| | |
|--|-------------------|
| Flammability (Solids): | No data available |
| Flash Point (Liquid) (°C): | |
| 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 |
| 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: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. Routes of exposure: eye contact, skin contact

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

Quil-A saponin

Rat IV LD50 670 ug/kg

Gentamicin

Rat Oral LD50 6600 mg/kg

Rat Subcutaneous LD50 710mg/kg

Mouse IM LD50 167 mg/kg

Rat IM LD50 463 mg/kg

Inhalation Acute Toxicity Allergic reactions might occur based on effects of the individual components.

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

Gentamicin

Eye Irritation Rabbit Non-irritating

Skin Irritation / Sensitization May cause allergic reactions in susceptible individuals.

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,

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11. TOXICOLOGICAL INFORMATION

| | |
|-----------------------------------|---|
| Carcinogen Status: | None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. |
| Cholesterol IARC: | Group 3 (Not Classifiable) |
| Polyacrylic acid IARC: | Group 3 (Not Classifiable) |

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 |

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

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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 SDS contains all of the information required by the CPR.

Polyacrylic acid

| | |
|---|------------|
| 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 |

Quil-A saponin

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |

Dimethyldioctadecyl ammonium bromide

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| EU EINECS/ELINCS List | 223-037-6 |

Cholesterol

| | |
|---|------------|
| 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 | 200-353-2 |

Feline leukemia 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 for Drugs and Poisons: | Schedule 4 |
| EU EINECS/ELINCS List | 215-765-8 |

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16. OTHER INFORMATION

Data Sources: The data contained in this SDS 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 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

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