# MATERIAL SAFETY DATA SHEET



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

**Pfizer Animal Health**
**Pfizer Inc**
**235 East 42nd Street**
**New York, NY 10017**
**Poison Control Center Phone: 1-866-531-8896**
**Technical Services Phone: 1-800-366-5288**
**Emergency telephone number:**
**CHEMTREC (24 hours): 1-800-424-9300**
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Pfizer Ltd,**
**Kent**
**CT13 9NJ**
**United Kingdom**
**+00 44 (0)1304 616161**

**Emergency telephone number:**
**ChemSafe (24 hours): +44 (0)208 762 8322**

## Material Name: Feline Leukemia Vaccine, Killed Virus

**Trade Name:** LEUKOCELL 2
**Synonyms:** Feline Leukemia Vaccine, Killed Virus
**Chemical Family:** Mixture
**Intended Use:** Veterinary Vaccine

## 2. HAZARDS IDENTIFICATION

**Appearance:** Liquid solution

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Additional Hazard Information:**
**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. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

**EU Indication of danger:** Not classified

**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 | Classification | % |
|---|---|---|---|---|
| Quil-A saponin | 66594-14-7 | Not listed | Not Listed | * |
| Aluminum hydroxide gel | 21645-51-2 | 244-492-7 | Not Listed | * |
| Gentamicin | 1403-66-3 | 215-765-8 | Not Listed | ## |

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

| | | | | |
|---|---|---|---|---|
| Thimerosal | 54-64-8 | 200-210-4 | N; R50/53<br>R33<br>T+; R26/27/28 | <0.01 |

| Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | % |
|---|---|---|---|---|
| Feline leukemia virus | NOT ASSIGNED | Not listed | Not Listed | * |

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

**For the full text of the R phrases mentioned in this Section, see Section 16**

## 4. 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.

**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.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** As for primary cause of fire.

**Hazardous Combustion Products:** Not known

**Fire Fighting Procedures:** Dike and collect water used to fight fire.

**Fire / Explosion Hazards:** Not applicable

## 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**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.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**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

**General Handling:** Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing dust, vapor or mist. Use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE. 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.

**Storage Conditions:** Store as directed by product packaging.

**Storage Temperature:** 2-7°C

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Refer to available public information for specific member state Occupational Exposure Limits.**

**Aluminum hydroxide gel**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 1 mg/m$^3$ TWA |
| **Austria OEL - MAKs** | Listed |
| **Bulgaria OEL - TWA** | Listed |
| **Czech Republic OEL - TWA** | Listed |
| **Germany (DFG) - MAK** | 1.5 mg/m$^3$ MAK<br>4 mg/m$^3$ MAK |
| **Latvia OEL - TWA** | Listed |
| **Lithuania OEL - TWA** | Listed |
| **Poland OEL - TWA** | Listed |

**Gentamicin**

| | |
|---|---|
| **Bulgaria OEL - TWA** | Listed |

**Thimerosal**

| | |
|---|---|
| **ACGIH Threshold Limit Value (TWA)** | 0.01 mg/m$^3$ TWA |
| **ACGIH Threshold Limit Value (STEL)** | 0.03 mg/m$^3$ STEL |
| **ACGIH - Skin Absorption Designation** | Listed |
| **Australia STEL** | 0.03 mg/m$^3$ |
| **Australia TWA** | 0.01 mg/m$^3$ |
| **Austria OEL - MAKs** | Listed |
| **Belgium OEL - TWA** | Listed |
| **Bulgaria OEL - TWA** | Listed |
| **Bulgaria - Biological Exposure Limit:** | Listed |
| **Czech Republic OEL - TWA** | Listed |
| **Denmark OEL - TWA** | Listed |
| **Estonia OEL - TWA** | Listed |
| **Finland OEL - TWA** | Listed |
| **France OEL - TWA** | Listed |
| **Germany - Biological Exposure Limit:** | Listed |
| **Greece OEL - TWA** | Listed |
| **Hungary OEL - TWA** | Listed |
| **Ireland OEL - TWAs** | Listed |
| **Lithuania OEL - TWA** | Listed |
| **OSHA - Final PELS - TWAs:** | 0.01 mg/m$^3$ |
| **Poland OEL - TWA** | Listed |
| **Portugal OEL - TWA** | Listed |

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| **Romania - Biological Exposure Limit:** | Listed |
| **Slovak Republic - Biological Exposure Limit:** | Listed |
| **Slovenia OEL - TWA** | Listed |
| **Spain OEL - TWA** | Listed |
| **Sweden OEL - TWAs** | Listed |

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**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:** In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

**Physical State:** Liquid solution
**Color:** No data available.
**Molecular Formula:** Mixture
**Molecular Weight:** Mixture

**Solubility:** Soluble: Water (based on components)
**pH:** 7.0 +/- 1.5
**Boiling Point (°C):** >100°C
**Vapor Pressure (kPa):** Expected to be negligible
**Specific Gravity:** 1.0 +/-0.2

**Flash Point (Liquid) (°C):** Non-flammable
**Polymerization:** Will not occur

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.
**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

**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)**

## 11. TOXICOLOGICAL INFORMATION

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

**Quil-A saponin**
Rat IV LD50 670 ug/kg

**Aluminum hydroxide gel**
Rat Intraperitoneal 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.

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** 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).

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

## 15. REGULATORY INFORMATION

**OSHA Label:**
Non-hazardous in accordance with international standards for workplace safety.

**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.

**Quil-A saponin**

| | |
|---|---|
| **Australia (AICS):** | Listed |

**Aluminum hydroxide gel**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Listed |
| **Australia (AICS):** | Listed |
| **EU EINECS/ELINCS List** | 244-492-7 |

**Gentamicin**

| | |
|---|---|
| **California Proposition 65** | Aminoglycosides- developmental |
| **Australia (AICS):** | Listed |
| **Standard for the Uniform Scheduling for Drugs and Poisons:** | Schedule 4 |
| **EU EINECS/ELINCS List** | 215-765-8 |

**Thimerosal**

| | |
|---|---|
| **CERCLA/SARA 313 Emission reporting** | 1.0% Supplier notification limit |
| **California Proposition 65** | developmental toxicity, initial date 7/1/90 |
| **Inventory - United States TSCA - Sect. 8(b)** | Listed |
| **Australia (AICS):** | Listed |
| **REACH - Annex XVII - Restrictions on Certain Dangerous Substances:** | Use restricted. See item 18. |
| **EU EINECS/ELINCS List** | 200-210-4 |

## 16. OTHER INFORMATION

**Text of R phrases mentioned in Section 3**

R33 - Danger of cumulative effects.
R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**