

SAFETY DATA SHEET



1. Identification

Product identifier	Leukocell® 2
Other means of identification	
Synonyms	LEUKOCELL * LEUKOCELL 2 * Feline Leukemia Vaccine, Killed Virus
Recommended use	Veterinary vaccine
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Thimerosal		54-64-8	<0.1

Chemical name	Common name and synonyms	CAS number	%
Aluminum hydroxide gel		21645-51-2	*
Feline leukemia virus		NOT ASSIGNED	*
Gentamicin		1403-66-3	##
Quil-A saponin		66594-14-7	*

Composition comments ## Trace
 * Non-hazardous Ingredients
 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

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.

Ingestion Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. 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.

Indication of immediate medical attention and special treatment needed Treat symptomatically.

General information For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

 Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

 Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. Avoid accidental injection. Wash thoroughly after handling. When using, do not eat, drink or smoke. Wear personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store away from direct sunlight. @ 2 - 7°C (36 - 45°F). Do not freeze. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-2 (29 CFR 1910.1000)

Components	Type	Value
Thimerosal (CAS 54-64-8)	Ceiling	0.04 mg/m ³
	TWA	0.01 mg/m ³

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Aluminum hydroxide gel (CAS 21645-51-2)	TWA	1 mg/m ³	Respirable fraction.
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m ³	
	TWA	0.01 mg/m ³	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m ³
	TWA	0.01 mg/m ³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

US - California OELs: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US - Tennessee OELs: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

Control banding approach

Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Wear impervious gloves if skin contact is possible.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. 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.

Thermal hazards Not applicable.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance Liquid solution

Physical state Liquid.

Form Liquid.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH 6 - 8

Melting point/freezing point Not available.

Initial boiling point and boiling range > 212 °F (> 100 °C)

Flash point Non-flammable

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

Specific gravity 0.8 - 1.2

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Sunlight. High temperatures. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

Incompatible materials Strong oxidizing agents. This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected.

Skin contact Prolonged skin contact may cause temporary irritation.

Eye contact Direct contact with eyes may cause temporary irritation.

Thimerosal
Species: Rabbit
Severity: Mild

Gentamicin
Species: Rabbit
Severity: Non-irritating

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. 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.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
Aluminum hydroxide gel (CAS 21645-51-2)		
Acute		
Other		
LD50	Rat	150 mg/kg
Gentamicin (CAS 1403-66-3)		
Acute		
Intramuscular		
LD50	Mouse	167 mg/kg
	Rat	463 mg/kg
Oral		
LD50	Rat	6600 mg/kg
Subcutaneous		
LD50	Rat	710 mg/kg
Quil-A saponin (CAS 66594-14-7)		
Acute		
Intravenous		
LD50	Rat	670 ug/kg
Thimerosal (CAS 54-64-8)		
Acute		
Oral		
LD50	Mouse	91 mg/kg
	Rat	75 mg/kg
Subcutaneous		
LD50	Rat	98 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	

Eye Contact

Thimerosal

Species: Rabbit

Severity: Mild

Gentamicin

Species: Rabbit

Severity: Non-irritating

Respiratory or skin sensitization**Respiratory sensitization** Not a respiratory sensitizer.**Skin sensitization** This product contains merthiolate which is considered to be a skin sensitizer. This product is not expected to cause skin sensitization.**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.**Carcinogenicity** This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.**Developmental effects**

Gentamicin

75 mg/kg/day Embryo / Fetal Development, Developmental toxicity

Result: LOAEL

Species: Rat

Organ: Intramuscular

Specific target organ toxicity - single exposure Not classified.**Specific target organ toxicity - repeated exposure** Not classified.**Aspiration hazard** Not an aspiration hazard.**Further information** Allergic reactions are possible. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.**12. Ecological information****Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.**Persistence and degradability** No data is available on the degradability of this product.**Bioaccumulative potential** No data available.**Mobility in soil** No data available.**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.**13. Disposal considerations****Disposal instructions** Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. 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). Dispose of contents/container in accordance with local/regional/national/international regulations.**Local disposal regulations** Dispose in accordance with all applicable regulations.

Hazardous waste code	None known. This product contains trace quantities of mercury, releases to the environment should be avoided.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Thimerosal (CAS 54-64-8)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Thimerosal (CAS 54-64-8)

Listed: July 1, 1990

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	04-06-2017
Version #	01
Disclaimer	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. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.