SAFETY DATA SHEET



1. Identification

Product identifier LymeVax®

Other means of identification

Synonyms Borrelia Burgdorferi Bacterin * Lyme disease vaccine, killed borrelia bacterin

Recommended use Veterinary vaccine
Recommended restrictions Not for human use
Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company Name (US) Zoetis Inc.

100 Campus Drive, P.O. Box 651

Florham Park, New Jersey 07932 (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

Contact E-Mail VMIPSrecords@zoetis.com

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)

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. May cause eye irritation.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Material name: LymeVax® SDS US

3282 Version #: 01 Issue date: 06-28-2016

Chemical name	Common name and synonyms	CAS number	%
Aluminum hydroxide		21645-51-2	<5
Sodium chloride		7647-14-5	<5
Potassium phosphate		7778-77-0	<1
Borrelia Burgdorferi		Not established	*
Sodium phosphate, dibasic		7558-79-4	*
Thimerosal		54-64-8	##

Composition comments

Trace

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. 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

If inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. If symptoms persist, get medical attention.

Skin contact

Wash off immediately with soap and plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.

Eye contact

Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses.

Get medical attention immediately.

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.

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. 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.

Indication of immediate medical attention and special treatment needed

None known.

General information

IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Unsuitable extinguishing

Water spray. Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Do not use water jet.

media

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Firefighters should wear full protective clothing including self contained breathing apparatus.

Fire fighting

General fire hazards

During all fire fighting activities, wear appropriate protective equipment, including self-contained

equipment/instructions breathing apparatus. Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials. No unusual fire or explosion hazards noted. This product is a nonflammable aqueous solution.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Material name: LymeVax® SDS US Methods and materials for containment and cleaning up Ensure adequate ventilation. Remove sources of ignition.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth

and place into containers. Clean contaminated surface thoroughly.

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. Prevent release to the environment. For waste

disposal, see section 13 of the SDS.

Use appropriate containment to avoid environmental contamination. **Environmental precautions**

7. Handling and storage

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with Precautions for safe handling

eyes. Avoid contact with skin. Avoid accidental injection. Avoid breathing mist or vapor. Observe good industrial hygiene practices. Wash thoroughly after handling. Handle and open container with

care. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities Store in a cool, dry place out of direct sunlight. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. 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	Туре	Value	
Thimerosal (CAS 54-64-8)	Ceiling	0.04 mg/m3	
	TWA	0.01 mg/m3	
US. ACGIH Threshold Limit Value	s		
Components	Туре	Value	Form
Aluminum hydroxide (CAS 21645-51-2)	TWA	1 mg/m3	Respirable fraction.
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	
US. NIOSH: Pocket Guide to Chen	nical Hazards		
Components	Туре	Value	
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	

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.

Not available. Control banding approach

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.

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.

Material name: LymeVax® SDS US Other Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and

laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. Whenever excessive air

contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures

to below the OEL.

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

Physical state Liquid. Form Liquid.

ColorLight opaqueOdorNot available.Odor thresholdNot available.

pH 7 - 7.4

Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Flammability limit - upper

Not available.

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%)Not available.Vapor pressureNot available.Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Explosive properties Not explosive. **Oxidizing properties** Not oxidizing.

10. Stability and reactivity

ReactivityThe 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 Direct sources of heat. Contact with incompatible materials. Protect from freezing. Avoid exposure

to light, sunlight and elevated temperatures.

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

Material name: LymeVax®

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Prolonged skin contact may cause temporary irritation.

Sodium chloride Species: Rabbit

Severity: Mild

Eye contact Direct contact with eyes may cause temporary irritation.

Thimerosal Species: Rabbit

Severity: Mild

Sodium chloride Species: Rabbit

Severity: Moderate

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

Components	Species	Test Results	
Aluminum hydroxide (CAS 216	645-51-2)		
<u>Acute</u>			
Oral			
LD50	Rat	> 5000 mg/kg	
Potassium phosphate (CAS 77	778-77-0)		
<u>Acute</u>			
Oral			
LD50	Mouse	1700 mg/kg	
Sodium chloride (CAS 7647-14	4-5)		
<u>Acute</u>			
Oral			
LD50	Mouse	4000 mg/kg	
	Rat	3000 mg/kg	
Sodium phosphate, dibasic (C.	AS 7558-79-4)		
<u>Acute</u>			
Oral			
LD50	Rat	17 g/kg	
Thimerosal (CAS 54-64-8)			
<u>Acute</u>			
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	Direct contact with eyes may cause temporary irritation.		

Material name: LymeVax® SDS US

3282 Version #: 01 Issue date: 06-28-2016

irritation

Eye Contact

Thimerosal Species: Rabbit

Severity: Mild

Sodium chloride Species: Rabbit

Severity: Moderate

Respiratory or skin sensitization

Respiratory sensitizationBased on available data, the classification criteria are not met. **Skin sensitization**Based on available data, the classification criteria are not met.

Germ cell mutagenicityNo 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 available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects None known.

Further information The antigens included in this product are non-infectious. All have been prepared from killed or

inactivated preparations of microorganisms.

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. This product contains trace quantities of mercury, releases to the environment should be avoided.

Components Species Test Results

Sodium chloride (CAS 7647-14-5)

Aquatic

Crustacea EC50 Water flea (Daphnia magna) 340.7 - 469.2 mg/l, 48 hours
Fish LC50 Fathead minnow (Pimephales promelas) 6020 - 7070 mg/l, 96 hours

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 instructionsThis 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). Avoid release to the environment. Collect and reclaim or dispose in sealed containers at licensed

waste disposal site.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

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).

Material name: LymeVax® SDS US

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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 Not established. Annex II of MARPOL 73/78 and

the IBC Code

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.

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Sodium phosphate, dibasic (CAS 7558-79-4)

Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

No

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

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

Not regulated.

(SDWA)

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Sodium phosphate, dibasic (CAS 7558-79-4)

Thimerosal (CAS 54-64-8)

US. New Jersey Worker and Community Right-to-Know Act

Sodium phosphate, dibasic (CAS 7558-79-4)

Thimerosal (CAS 54-64-8)

US. Pennsylvania Worker and Community Right-to-Know Law

Sodium phosphate, dibasic (CAS 7558-79-4)

Thimerosal (CAS 54-64-8)

Material name: LymeVax® 7/8

3282 Version #: 01 Issue date: 06-28-2016

US. Rhode Island RTK

Sodium phosphate, dibasic (CAS 7558-79-4)

Thimerosal (CAS 54-64-8)

US. California Proposition 65

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
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

^{*}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).

Toxic Substances Control Act (TSCA) Inventory

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

Issue date 06-28-2016

Version # 01

United States & Puerto Rico

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.

Material name: LymeVax® SDS US

No