



MATERIAL SAFETY DATA SHEET

Revision date: 23-Oct-2009

Version: 2.0

Page 1 of 9

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
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Leptospira Hardjo Bacterin

Trade Name:	Spirovac®
Chemical Family:	Not determined
Intended Use:	Veterinary Vaccine

2. HAZARDS IDENTIFICATION

Appearance: Liquid solution in multiple-dose vials
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

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.
Irritant

EU Indication of danger:

EU Hazard Symbols:
Xi



EU Risk Phrases:

Australian Hazard Classification (NOHSC):

R43 - May cause sensitization by skin contact.
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.

MATERIAL SAFETY DATA SHEET

Material Name: Leptospira Hardjo Bacterin
Revision date: 23-Oct-2009

Page 2 of 9
Version: 2.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Formaldehyde	50-00-0	200-001-8	C;R34 Carc. Cat.3;R40 R43 T;R23/24/25	<0.1
Merthiolate (as mercury)	54-64-8	200-210-4	N; R50/53 R33 T+; R26/27/28	##

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Aluminum hydroxide	21645-51-2	244-492-7	Not Listed	*
Leptospira borgpeterseni serovar hardjo	NOT ASSIGNED	Not listed	Xn;R22	*
Saline suspension	MIXTURE	Not listed	Not Listed	>90

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:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

MATERIAL SAFETY DATA SHEET

Material Name: Leptospira Hardjo Bacterin
Revision date: 23-Oct-2009

Page 3 of 9
Version: 2.0

Additional Information: This product is a nonflammable aqueous solution. This material is not expected to support combustion.

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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 vapor or mist. Use appropriate personal protective equipment.

Storage Conditions: Store under refrigeration in closed container.

Storage Temperature: 2-7°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Aluminum hydroxide

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
	4 mg/m ³ MAK
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Poland OEL - TWA	Listed

Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Listed
Australia STEL	2 ppm
	2.5 mg/m ³
Australia TWA	1 ppm
	1.2 mg/m ³
Austria OEL - MAKs	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed

MATERIAL SAFETY DATA SHEET

Material Name: Leptospira Hardjo Bacterin
Revision date: 23-Oct-2009

Page 4 of 9
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany (DFG) - MAK	0.3 ppm MAK 0.37 mg/m ³ MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Japan - OELs - Ceilings	0.2 ppm 0.24 mg/m ³
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	0.75 ppm
OSHA - Specifically Regulated Chemicals	0.5 ppm-Action Level 0.75 ppm-TWA 2 ppm-STEL
Poland OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Sweden OEL - TWAs	Listed
Merthiolate (as mercury)	
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
Romania - Biological Exposure Limit:	Listed
Slovak Republic - Biological Exposure Limit:	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

See exposure limits for component (s) listed above.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Leptospira Hardjo Bacterin
Revision date: 23-Oct-2009

Page 5 of 9
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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. Wash hands and arms thoroughly after handling this material.

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:	Aqueous liquid suspension	Solution	Color:	No data available.
Molecular Formula:	Mixture		Molecular Weight:	Mixture
Solubility:	Miscible: Water			
pH:	7.0 +/- 1.5			
Melting/Freezing Point (°C):	-0.5			
Boiling Point (°C):	100			
Vapor Pressure (kPa):	3.19 (25 °C)			
Specific Gravity:	1.01			
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 primary hazards are due to the formaldehyde content.

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

Merthiolate (as mercury)

Rat Oral LD50 75 mg/kg
Rat Subcutaneous LD50 98 mg/kg

Formaldehyde

Rat Oral LD50 800 mg/kg

MATERIAL SAFETY DATA SHEET

Material Name: Leptospira Hardjo Bacterin
Revision date: 23-Oct-2009

Page 6 of 9
Version: 2.0

11. TOXICOLOGICAL INFORMATION

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

Merthiolate (as mercury)

Eye Irritation Rabbit Mild

Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

Skin Irritation / Sensitization

This product contains formaldehyde and merthiolate which are considered to be skin sensitizers.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs

90 Day(s) Rat Inhalation Not Specified Lungs

90 Day(s) Monkey Inhalation Not Specified Lungs

9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

Rats exposed to 15 ppm formaldehyde vapor for six hours/day for up to nine days showed an acute cell degeneration, necrosis and inflammation in the nasal cavities. Inhalation exposure to formaldehyde for up to 90 days produced interstitial inflammation in the lungs of dogs, rats, monkeys, rabbits and guinea pigs.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity

Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Formaldehyde

In Vitro Bacterial Mutagenicity (Ames) Bacteria Positive

In Vitro Chromosome Aberration Rodent Positive

In Vitro Sister Chromatid Exchange Rodent Positive

In Vivo Chromosome Aberration Not specified Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors

2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

Carcinogen Status:

Contains formaldehyde: potential cancer hazard.

Formaldehyde

IARC: Group 1

NTP: Listed

OSHA: Present

MATERIAL SAFETY DATA SHEET

Material Name: Leptospira Hardjo Bacterin
Revision date: 23-Oct-2009

Page 7 of 9
Version: 2.0

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 Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Aluminum hydroxide

MATERIAL SAFETY DATA SHEET

Material Name: Leptospira Hardjo Bacterin
Revision date: 23-Oct-2009

Page 8 of 9
Version: 2.0

15. REGULATORY INFORMATION

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

Formaldehyde

CERCLA/SARA 313 Emission reporting	0.1% de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb TPQ
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen, initial date 1/1/88 (gas)
	0.5 ppm-Action Level
	0.75 ppm-TWA
	2 ppm-STEL
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 6
	200-001-8

Merthiolate (as mercury)

CERCLA/SARA 313 Emission reporting	1.0% Supplier notification limit
California Proposition 65	Developmental
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.

R34 - Causes burns.

R40 - Limited evidence of a carcinogenic effect

R43 - May cause sensitization by skin contact.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. 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

MATERIAL SAFETY DATA SHEET

Material Name: Leptospira Hardjo Bacterin
Revision date: 23-Oct-2009

Page 9 of 9
Version: 2.0

Pfizer 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