



MATERIAL SAFETY DATA SHEET

Revision date: 23-Oct-2009

Version: 1.4

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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: Spirovac VL5 (Campylobacter fetus-Leptospira canicola-grippotyphosa-hardjo-icterhaemorrhagiae-pomona Bacterin)

Trade Name: Spirovac VL5
Chemical Family: Mixture
Intended Use: Veterinary Vaccine

2. HAZARDS IDENTIFICATION

Appearance: Opaque light brown to gray liquid

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.

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 | % |
|--------------------------|------------|-----------------------|-----------------------------------|----|
| 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 | % |
|------------|------------|-----------------------|----------------|---|
|------------|------------|-----------------------|----------------|---|

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| | | | | |
|--------------------------------|--------------|------------|------------|---|
| Campylobacter fetus | NOT ASSIGNED | Not listed | Not Listed | * |
| Leptospira canicola | NOT ASSIGNED | Not listed | Not Listed | * |
| Leptospira grippotyphosa | NOT ASSIGNED | Not listed | Not Listed | * |
| Leptospira hardjo | NOT ASSIGNED | Not listed | Not Listed | * |
| Leptospira icterohaemorrhagiae | NOT ASSIGNED | Not listed | Not Listed | * |
| Leptospira pomona | 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: | During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. |
| 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. |

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7. HANDLING AND STORAGE

General Handling: Use with adequate ventilation. Use appropriate personal protective equipment. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing.

Storage Conditions: Store under refrigeration in closed container.

Storage Temperature: 2-7°C (35 to 45°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

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.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Rubber gloves

Eyes: Safety glasses or goggles

Skin: Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 | Color: | Light brown to gray |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| Solubility: | Aqueous solution | | |
| pH: | 7.0 +/- 1.5 | | |
| Specific Gravity: | 1.01-1.03 | | |
| 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.

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

Merthiolate (as mercury)

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

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

Merthiolate (as mercury)

Eye Irritation Rabbit Mild
No data available

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.

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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

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.

Merthiolate (as mercury)

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

REACH - Annex XVII - Restrictions on Certain

Dangerous Substances:

EU EINECS/ELINCS List

1.0% Supplier notification limit

Developmental

Listed

Listed

Use restricted. See item 18.

200-210-4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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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: 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 5 - Fire Fighting 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

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End of Safety Data Sheet