

SAFETY DATA SHEET



Revision date: 27-May-2015

Version: 3.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: ENCEPHALOMYELITIS-INFLUENZA VACCINE, EASTERN AND WESTERN, KILLED VIRUS, TETANUS TOXOID

Trade Name: Fluvac Innovator 4, Fluvac Innovator EWT
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary Vaccine
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Pink to milky red liquid
Classification of the Substance or Mixture
GHS - Classification Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Short Term: 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.

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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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 | EU Classification | GHS Classification | % |
|--------------------|------------|-----------------------|------------------------------------|--|------|
| Sodium bicarbonate | 144-55-8 | 205-633-8 | Not Listed | Not Listed | <1 |
| Thimerosal | 54-64-8 | 200-210-4 | T+; R26/27/28; R33 N; R50/53 | Acute Tox.2 (H300) Acute Tox. 1(H310) STOT RE 2 (H373) Acute Tox.2 (H330) Acute Aquatic 1 (H400) Chronic Aquatic 1 (H410) | <0.1 |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--|--------------|-----------------------|-------------------|--------------------|---|
| 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid | 7365-45-9 | 230-907-9 | Not Listed | Not Listed | * |
| EASTERN EQUINE ENCEPHALOMYELITIS | Not Assigned | Not Listed | Not Listed | Not Listed | * |
| WESTERN EQUINE ENCEPHALOMYELITIS | Not Assigned | Not Listed | Not Listed | Not Listed | * |
| Equine Influenza Virus, Kentucky 97 (EIV) | Not Assigned | Not Listed | Not Listed | Not Listed | * |
| Clostridium tetani toxoid | Not assigned | Not Listed | Not Listed | Not Listed | * |
| Squalene | 111-02-4 | 203-826-1 | Not Listed | Not Listed | * |
| Water for injection | 7732-18-5 | 231-791-2 | Not Listed | Not Listed | * |

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

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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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.

Specific end use(s): No data available

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Sodium bicarbonate

Czech Republic OEL - TWA

5 mg/m³

Latvia OEL - TWA

5 mg/m³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

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:

Wear safety glasses or goggles if eye contact is possible.

Skin:

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

Respiratory protection:

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Liquid

Color:

Pink to milky red

Odor:

No data available.

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

pH:

No data available.

Melting/Freezing Point (°C):

No data available.

Boiling Point (°C):

No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

Decomposition Temperature (°C):

No data available.

Evaporation Rate (Gram/s):

No data available

Vapor Pressure (kPa):

No data available

Vapor Density (g/ml):

No data available

Relative Density:

No data available

Viscosity:

No data available

Flammability:

Autoignition Temperature (Solid) (°C):

No data available

Flammability (Solids):

No data available

Flash Point (Liquid) (°C):

Non-flammable

Upper Explosive Limits (Liquid) (% by Vol.):

No data available

Lower Explosive Limits (Liquid) (% by Vol.):

No data available

Polymerization:

Will not occur

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10. STABILITY AND REACTIVITY

| | |
|---|--|
| Reactivity: | No data available |
| Chemical Stability: | Stable under normal conditions of use. |
| Possibility of Hazardous Reactions | |
| Oxidizing Properties: | None |
| Conditions to Avoid: | Fine particles (such as dust and mists) may fuel fires/explosions. |
| Incompatible Materials: | This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals. |
| Hazardous Decomposition Products: | No data available |

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. Routes of exposure: eye contact , skin contact

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

Thimerosal

Rat Oral LD50 75 mg/kg
Mouse Oral LD50 91 mg/kg
Rat Subcutaneous LD50 98mg/kg

Sodium bicarbonate

Rat Oral LD50 4220 mg/kg
Mouse Oral LD50 3360mg/kg
Rat Inhalation LC50 > 900mg/m³

Inhalation Acute Toxicity Allergic reactions might occur based on effects of the individual components.

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

Thimerosal

Eye Irritation Rabbit Mild

Sodium bicarbonate

Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Slight

Skin Irritation / Sensitization May cause allergic reactions in susceptible individuals. This product contains merthiolate which is considered to be a skin sensitizer.

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. This product contains trace quantities of mercury, releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sodium bicarbonate

Daphnia magna (Water Flea) EC50 48 Hours 2350 mg/L
Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 8250 mg/L
Gambusia affinis (Mosquitofish) LC50 96 Hours 7550 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

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15. REGULATORY INFORMATION

WHMIS hazard class:

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

Sodium bicarbonate

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 205-633-8 |

4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 230-907-9 |

EASTERN EQUINE ENCEPHALOMYELITIS

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

WESTERN EQUINE ENCEPHALOMYELITIS

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Equine Influenza Virus, Kentucky 97 (EIV)

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Clostridium tetani toxoid

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Squalene

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |

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EU EINECS/ELINCS List 203-826-1

Water for injection

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 231-791-2 |

Thimerosal

| | |
|--|------------------------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| 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 and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
Acute toxicity, dermal-Cat.1; H310 - Fatal in contact with skin
Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

T+ - Very toxic
N - Dangerous for the environment

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: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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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.

End of Safety Data Sheet