

SAFETY DATA SHEET



1. Identification

| | |
|--|---|
| Product identifier | Fluvac Innovator |
| Other means of identification | |
| Synonyms | Fluvac * FLUVAC® INNOVATOR * Fluvac Innovator® * Equine Influenza Vaccine, Killed Virus |
| Recommended use of the chemical and restrictions on use | |
| Recommended use | Veterinary vaccine |
| Restrictions on use | Not for human use |
| Details of manufacturer or importer | |
| Company Name (AU) | Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA |
| Tel | 1800 814 883 |
| Fax | (02) 8876 0444 |
| Email | australia.animalhealth@zoetis.com |
| Emergency Phone | 1800 814 883 (all hours) |
| Police and Fire Brigade | Dial 000 |
| If ineffective | Dial Poisons Information Centre (13 1126 from anywhere in Australia) |

2. Hazard(s) identification

Classification of the hazardous chemical

| | |
|------------------------------|-----------------|
| Physical hazards | Not classified. |
| Health hazards | Not classified. |
| Environmental hazards | Not classified. |

Label elements, including precautionary statements

| | |
|-----------------------------------|--|
| Hazard symbol(s) | None. |
| Signal word | None. |
| Hazard statement(s) | The mixture does not meet the criteria for classification. |
| Precautionary statement(s) | |
| 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. |

Other hazards which do not result in classification None known.

Supplemental information Direct contact with eyes may cause temporary irritation. In the event of accidental injection, an allergic reaction may occur.

3. Composition/information on ingredients

Mixture

| Identity of chemical ingredients | CAS number and other unique identifiers | Concentration of ingredients (%) |
|--------------------------------------|---|----------------------------------|
| Equine Influenza Virus, Killed Virus | Not assigned | * |
| Neomycin B | 119-04-0 | ## |
| Polymyxin B | 1404-26-8 | ## |
| Thimerosal | 54-64-8 | ## |

Composition comments ## Trace
 * Non-hazardous Ingredients

4. First-aid measures

Description of necessary 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 centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Personal protection for first-aid responders 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.

Symptoms caused by exposure 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.

Medical attention and special treatment Treat symptomatically.

5. Fire-fighting measures

Extinguishing media

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 fire fighters 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.

Hazchem Code None.

General fire hazards No unusual fire or explosion hazards noted.

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

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

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.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. 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 out of direct sunlight in dark, dry conditions. @ 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 and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components

| Components | Type | Value |
|---------------------------|------|-----------------------|
| Neomycin B (CAS 119-04-0) | TWA | 100 µg/m ³ |

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components

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

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components

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

US. ACGIH Threshold Limit Values

Components

| 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

Australia 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.

Control banding approach

Polymyxin B: Zoetis OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

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, for example personal protective equipment (PPE)

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 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.

Hygiene measures

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. |
| Colour | Pale yellow - Red White. |

Odour Odourless.

Odour threshold Not available.

pH 6 - 8

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

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.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) 100 %

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

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other physical and chemical parameters

Explosive properties Not explosive.

Oxidising properties Not oxidising.

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. Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on possible 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.

Eye contact
Thimerosal

Species: Rabbit
Severity: Mild

Ingestion

Expected to be a low ingestion hazard.

Symptoms related to exposure

Direct contact with eyes 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.

Acute toxicity

| Components | Species | Test results |
|-----------------------------|---------|--------------|
| Neomycin B (CAS 119-04-0) | | |
| Acute | | |
| Intravenous | | |
| LD50 | Mouse | 24 mg/kg |
| Oral | | |
| LD50 | Rat | 1250 mg/kg |
| Polymyxin B (CAS 1404-26-8) | | |
| Acute | | |
| Oral | | |
| LD50 | Mouse | 790 mg/kg |
| Other | | |
| LD50 | Mouse | 3980 ug/kg |
| Subcutaneous | | |
| LD50 | Rat | 50 mg/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/irritation

Direct contact with eyes may cause temporary irritation.

Eye contact

Thimerosal

Species: Rabbit
Severity: Mild

Respiratory or skin sensitisation

Respiratory sensitisation

Not a respiratory sensitizer.

Skin sensitisation

This product contains merthiolate which is considered to be a skin sensitizer. This product is not expected to cause skin sensitisation.

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Polymyxin B

In vitro
Result: negative

In vivo
Result: negative

Carcinogenicity

Based on available data, the classification criteria are not met.

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. |
| Other 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. |

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 for this product. |
| 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 methods | Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. 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. Dispose of contents/container in accordance with local/regional/national/international regulations. |
| Residual waste | 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

| | |
|---|-----------------------------------|
| ADG | Not regulated as dangerous goods. |
| RID | 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

Safety, health and environmental regulations

National regulations This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA Approval No: PERMIT NUMBER – PER84235

Australia Medicines & Poisons Appendix E

Mercury, organic compounds (CAS 54-64-8)

Australia Medicines & Poisons Appendix G

Mercury (CAS 54-64-8)

Australia Medicines & Poisons Schedule 2

Mercury (CAS 54-64-8)

Australia Medicines & Poisons Schedule 4

Framycetin (CAS 119-04-0)

Australia Medicines & Poisons Schedule 7

MERCURY, EXCEPT WHEN SEPARATELY SPECIFIED IN THIS SCHEDULE (CAS 54-64-8)

Australia National Pollutant Inventory (NPI): Threshold quantity

Thimerosal (CAS 54-64-8) 5 kg Threshold Category: 1B

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Thimerosal (CAS 54-64-8) 2000 TONNES/YR Threshold Category: 2B

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Thimerosal (CAS 54-64-8) Pesticide

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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 |
| 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

| | |
|----------------------|--|
| Issue date | 15-April-2017 |
| Revision date | 08-January-2018 |
| 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

Regulatory information: National regulations