SAFETY DATA SHEET



1. Identification

Product identifier Fluvac Innovator 4

Other means of identification

Synonyms Fluvac Innovator® 4 * FLUVAC® INNOVATOR 4 * Fluvac Innovator EWT *

Encephalomyelitis-Influenza Vaccine, Eastern & Western, Killed Virus, Tetanus Toxoid

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

Company Name (US) Zoetis Inc.

10 Sylvan Way

Parsippany, New Jersey 07054 (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

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)

None known.

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

allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing

products may cause severe vasospasm following accidental injection.

3. Composition/information on ingredients

Mixtures

Material name: Fluvac Innovator 4 SDS US

Chemical name	Common name and synonyms	CAS number	%
Squalene		111-02-4	<10
Clostridium tetani toxoid		Not assigned	*
EASTERN EQUINE ENCEPHALOMYELITIS		Not Assigned	*
Equine Influenza Virus, Kentucky 97 (EIV)		Not Assigned	*
Neomycin B		119-04-0	##
Polymyxin B		1404-26-8	##
Thimerosal		54-64-8	##
WESTERN EQUINE ENCEPHALOMYELITIS		Not Assigned	*

Composition comments

Trace

* Non-hazardous Ingredients

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

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

Most important

symptoms/effects, acute and

delayed

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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

Indication of immediate medical attention and special treatment needed

treatment needed

General information

Treat symptomatically. Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome.

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.

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media

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

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 firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

Move containers from fire area if you can do so without risk.

equipment/instructions Specific methods

General fire hazards

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

No unusual fire or explosion hazards noted.

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: Fluvac Innovator 4
730 Version #: 01 Issue date: 04-16-2017

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.

Environmental precautions

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

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. 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/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Components	Туре	Value	
Neomycin B (CAS 119-04-0)	TWA	100 μg/m3	
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	
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3	
,			
	TWA	0.01 mg/m3	
US. NIOSH: Pocket Guide to Cher		<u> </u>	
US. NIOSH: Pocket Guide to Cher Components		<u> </u>	
	nical Hazards	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.

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, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Material name: Fluvac Innovator 4

SDS US

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.

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 stateLiquid.FormLiquid.

Color Pink to milky red
Odor Not available.
Odor threshold Not available.
pH Not available.
Melting point/freezing point Not available.
Initial boiling point and boiling Not available.

range

Flash point Non-flammable
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.

Vapor pressure Not 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 propertiesNot 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.

730 Version #: 01 Issue date: 04-16-2017

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 oxidizing agents. This material can be denatured or inactivated by a variety of organic

solvents, salts or heavy metals.

Hazardous decomposition

products

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected.

Skin contact Prolonged skin contact may cause temporary irritation.

Eye contactDirect contact with eyes may cause temporary irritation.
Thimerosal
Species: Rabbit

Species: Rabbit Severity: Mild

Ingestion Expected to be a low ingestion hazard.

Species

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.

Test Results

Information on toxicological effects

Acute toxicity Components

Components	Species	rest nesuits	
Neomycin B (CAS 119-04-0)			
<u>Acute</u>			
Intravenous			
LD50	Mouse	24 mg/kg	
Oral			
LD50	Rat	1250 mg/kg	
Polymyxin B (CAS 1404-26-8)			
<u>Acute</u>			
Oral			
LD50	Mouse	790 mg/kg	
Other			
LD50	Mouse	3980 ug/kg	
Subcutaneous			
LD50	Rat	50 mg/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 contac	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Direct contact with eye	Direct contact with eyes may cause temporary irritation.	
Eye Contact			
Thimerosal	Species: Rabbit Severity: Mild		

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Material name: Fluvac Innovator 4

Skin sensitization This product contains merthiolate which is considered to be a skin sensitizer. This product is not

expected to cause skin sensitization.

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 This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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 Prolonged inhalation may be harmful.

Further 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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm

following accidental injection.

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. No data available.

Mobility in soil
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 instructionsAvoid 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. 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). Dispose of

contents/container in accordance with local/regional/national/international regulations.

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

should be avoided.

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).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

Material name: Fluvac Innovator 4

SDS US

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.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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

(SDWA)

Not regulated.

US state regulations 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

Material name: Fluvac Innovator 4

Country(s) or region Inventory name On inventory (yes/no)*

KoreaExisting Chemicals List (ECL)NoNew ZealandNew Zealand InventoryNo

Philippine Inventory of Chemicals and Chemical Substances

(PICCS)

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, including date of preparation or last revision

Issue date 04-16-2017

Version # 01

Philippines

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 This document has undergone significant changes and should be reviewed in its entirety.

Material name: Fluvac Innovator 4 SDS US

No