

SAFETY DATA SHEET



1. Identification

Product identifier	Fluvac Innovator 5
Other means of identification	
Synonyms	Fluvac Innovator® 5 * FLUVAC® INNOVATOR 5 * Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine Eastern and Western, Killed Virus, Tetanus Toxoid
Recommended use	Veterinary vaccine
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	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 (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental 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.

Other hazards 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

Chemical name	Common name and synonyms	CAS number	%
Squalene		111-02-4	<10
Formaldehyde		50-00-0	<0.1
Clostridium tetani toxoid		Not assigned	*
EASTERN EQUINE ENCEPHALOMYELITIS		Not assigned	*
Equine Influenza Virus, Kentucky 97 (EIV)		Not assigned	*
Inactivated Equine Herpes virus type 1		Not assigned	*
Inactivated Equine Herpes virus type 4		Not assigned	*
Neomycin B		119-04-0	##
Polymyxin B		1404-26-8	##
Sodium O-(ethylmercurithio)benzoate		54-64-8	##
WESTERN EQUINE ENCEPHALOMYELITIS		Not assigned	*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments

Trace

* Non-hazardous Ingredients

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 centre 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

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.

General information

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

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 firefighters

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.

Specific methods

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

General fire hazards

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.

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

Environmental precautions

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/personal protection

Occupational exposure limits

Zoetis

Components

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

US. ACGIH Threshold Limit Values

Components

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m ³
	TWA	0.01 mg/m ³

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	1.3 mg/m ³
	TWA	1 ppm 0.9 mg/m ³ 0.75 ppm
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m ³
	TWA	0.01 mg/m ³

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	1 ppm
	TWA	0.3 ppm
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m ³
	TWA	0.01 mg/m ³

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	1.5 ppm
	STEL	1 ppm
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	3 mg/m3
		2 ppm
Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0.3 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines**Canada - Alberta OELs: Skin designation**

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - British Columbia OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - Manitoba OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - Ontario OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - Quebec OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

Canada - Saskatchewan OELs: Skin designation

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Sodium O-(ethylmercurithio)benzoate (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.

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	suspension
Physical state	Liquid.
Form	Liquid.
Colour	Pink
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
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. 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.
Formaldehyde Species: Rabbit
Severity: Moderate Severe

Eye contact Direct contact with eyes may cause temporary irritation.
Sodium O-(ethylmercurithio)benzoate Species: Rabbit
Severity: Mild

Formaldehyde Species: Rabbit
Severity: Severe

Ingestion Expected to be a low ingestion hazard.

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.

Information on toxicological effects

Acute toxicity

Components	Species	Test results
Formaldehyde (CAS 50-00-0)		
Acute		
Oral		
LD50	Rat	800 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumours
	Rat	15 ppm, 9 days Respiratory system
		6 ppm, 2 years Tumours
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

Components	Species	Test results
Sodium O-(ethylmercurithio)benzoate (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/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye contact		
Sodium O-(ethylmercurithio)benzoate	Species: Rabbit	Severity: Mild
Formaldehyde	Species: Rabbit	Severity: Severe
Respiratory or skin sensitisation		
ACGIH sensitisation		
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization	Respiratory sensitisation
Canada - British Columbia OELs: Respiratory or skin sensitiser		
Formaldehyde (CAS 50-00-0)	Capable of causing respiratory, dermal or conjunctival sensitization.	
Canada - Manitoba OELs Hazard: Dermal sensitization		
Formaldehyde (CAS 50-00-0)	Dermal sensitization	
Canada - Manitoba OELs Hazard: Respiratory sensitization		
Formaldehyde (CAS 50-00-0)	Respiratory sensitisation	
Canada - Saskatchewan OELs Hazard Data: Sensitiser		
Formaldehyde (CAS 50-00-0)	Sensitiser.	
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		
Formaldehyde	In Vitro Bacterial Mutagenicity (Ames) Result: positive Species: Bacteria	
	In Vitro Chromosome Aberration Result: positive Species: Rodent	
	In Vitro Sister Chromatid Exchange Result: positive Species: Rodent	
Polymyxin B	In vitro Result: negative	
Formaldehyde	In Vivo Chromosome Aberration Result: positive Species: Not specified	
Polymyxin B	In vivo Result: negative	

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. No known carcinogens are present at greater than 0.1%.

ACGIH Carcinogens

Formaldehyde (CAS 50-00-0) A2 Suspected human carcinogen.

Canada - Alberta OELs: Carcinogen category

Formaldehyde (CAS 50-00-0) Suspected human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Formaldehyde (CAS 50-00-0) Suspected human carcinogen.

Canada - Quebec OELs: Carcinogen category

Formaldehyde (CAS 50-00-0) Suspected carcinogenic effect in humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0) 1 Carcinogenic to humans.

US. National Toxicology Program (NTP) Report on Carcinogens

Formaldehyde (CAS 50-00-0) Known To Be Human Carcinogen.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Developmental effects

Formaldehyde 185 mg/kg/day Embryo / Fetal Development, Not teratogenic
Maternal toxicity
Species: Mouse
Organ: Oral

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

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

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.

Components	Species	Test results
Formaldehyde (CAS 50-00-0)		
Aquatic		
Crustacea	EC50 Water flea (Daphnia pulex)	4.3 - 7.8 mg/l, 48 hours
Fish	LC50 Striped bass (Morone saxatilis)	10.302 - 16.743 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

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 instructions 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.

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.

14. Transport information

TDG	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

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

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8) Substance subject to notification or consent.

Greenhouse Gases

Not listed.

Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)

Formaldehyde (CAS 50-00-0)

Sodium O-(ethylmercurithio)benzoate (CAS 54-64-8)

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Sodium O-(ethylmercurithio)benzoate (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

Country(s) or region	Inventory name	On inventory (yes/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	16-April-2017
Version No.	01
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	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients