SAFETY DATA SHEET



1. Identification

Product identifier BURSAPLEX Vaccine

Other means of identification

Synonyms Poulvac® Bursaplex® * BURSAPLEX * Bursal Disease Vaccine, Live Virus

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 &

Drug Safety

1-866-531-8896

Product Support/Technical

Services

1-888-963-8471

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

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail productsupport@zoetis.com

1-800-461-0917 **Product Support**

All Safety Data Sheets are available via our Zoetis Canada website at

https://www.zoetis.ca/sds/sds.aspx

Not available. **Supplier**

2. Hazard identification

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

Label elements

Hazard symbol None. Signal word None.

The mixture does not meet the criteria for classification. **Hazard statement**

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.

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

allergic reaction may occur.

Other hazards None known.

3. Composition/information on ingredients

Mixtures

Material name: BURSAPLEX Vaccine SDS CANADA 1/6

Chemical name	Common name and synonyms	CAS number	%
Gentamicin		1403-66-3	##
Infectious bursal disease virus		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.

Eve 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 unconsious 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.

Indication of immediate medical attention and special treatment needed

Treat symptomatically.

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. IF exposed or concerned: Get medical advice/attention.

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

equipment/instructions

Use water spray to cool unopened containers.

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. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Extinguish all flames in the vicinity. Ensure adequate ventilation. Avoid release to the environment.

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. Clean surface thoroughly to remove residual contamination.

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 breathing mist or vapour. Avoid contact with eyes, skin, and clothing. When using, do not eat, drink or smoke. Wear personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Avoid accidental injection.

Conditions for safe storage, including any incompatibilities Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze. Store away from incompatible materials (see Section 10 of the SDS). Store in a cool, dry place out of direct sunlight. Keep away from heat, sparks and open flame.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

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

Control banding approach

Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m3 to < 1000ug/m3)

Appropriate engineering

Keep air contamination levels below the exposure limits or within the OEB range listed above in

controls

this section. 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 appropriate chemical resistant gloves. 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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to

control exposures to the bottom of the OEB range.

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

Physical state Solid. Solid. Form

Not available. Colour Odourless. Odour Not available. Melting point/freezing point Boiling point or initial boiling Not available.

point and boiling range

Not available.

Upper/lower flammability or explosive limits

Explosive limit - lower (%) Not available. Not available. Explosive limit - upper

(%)

Flammability

Not available. Flash point **Auto-ignition temperature** Not available. **Decomposition temperature** Not available.

7 pН

Kinematic viscosity Not available.

Solubility

Solubility (water) 100 %

Partition coefficient

Not available.

(n-octanol/water) (log value)

Not available. Vapour pressure Density and/or relative density Not available. Vapour density Not available. **Particle characteristics** Not available.

Other information

Explosive properties Not explosive. Oxidising properties Not oxidising.

Material name: BURSAPLEX Vaccine

Version #: 02 Revision date: 28-March-2024 Issue date: 17-April-2017

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 Sunlight. Contact with incompatible materials. Store at 2-7°C. Prolonged exposure to higher

temperatures may adversely affect potency. Do not freeze.

This material can be denatured or inactivated by a variety of organic solvents, salts or heavy Incompatible materials

metals.

Hazardous decomposition

products

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

No adverse effects due to inhalation are expected. Inhalation

Skin contact Prolonged skin contact may cause temporary irritation. In the event of accidental

injection, an allergic reaction may occur.

Direct contact with eyes may cause temporary irritation. Eve contact

Gentamicin Species: Rabbit

Severity: Non-irritating

Ingestion May cause discomfort if swallowed. However, ingestion is not likely to be a primary

route of occupational exposure.

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 Expected to be a low hazard for usual industrial or commercial handling by trained

personnel.

Components **Species** Test Results

Gentamicin (CAS 1403-66-3)

Acute

Intramuscular

LD50 Mouse 167 mg/kg Rat 463 mg/kg

Oral LD50

Rat

6600 mg/kg

Subcutaneous

LD50 Rat 710 mg/kg

Skin corrosion/irritation Serious eye damage/eye

irritation

Prolonged skin contact may cause temporary irritation.

Direct contact with eyes may cause temporary irritation.

Eye contact

Gentamicin

Species: Rabbit Severity: Non-irritating

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitiser.

This product is not expected to cause skin sensitisation. Skin sensitisation

No data available to indicate product or any components present at greater than 0.1% are Germ cell mutagenicity

mutagenic or genotoxic.

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

Due to partial or complete lack of data the classification is not possible.

Material name: BURSAPLEX Vaccine Version #: 02 Revision date: 28-March-2024 Issue date: 17-April-2017 Reproductive toxicity

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

Developmental effects

Gentamicin

75 mg/kg/day Embryo / Fetal Development, Developmental

toxicity

Result: LOAEL Species: Rat

Organ: Intramuscular

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 attenuated preparations of microorganisms.

12. Ecological information

Ecotoxicity Avoid release to the environment. 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.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Mobility in soil

This product is completely water soluble and will disperse 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.

Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.

Local disposal regulations

Hazardous waste code

Dispose in accordance with all applicable regulations.

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company. None known.

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.

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

Not applicable.

the IBC Code

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)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

Country(s) or region

International Inventories

Australia	Australian Inventory of Industrial Chemicals (AICIS)	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	No

(PICCS)

Inventory name

Taiwan Chemical Substance Inventory (TCSI)

United States & Puerto Rico

Toxic Substances Control Act (TSCA) Inventory

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information

Issue date17-April-2017Revision date28-March-2024

Version No. 02

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

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On inventory (yes/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).