SAFETY DATA SHEET



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Bursine®-2

Section 1. Identification

Product identifier : Bursine®-2

Other means of : Bursal Disease Vaccine, Live Virus identification : Poulvac Bursine-2

Product type : Powder.

Relevant identified uses of the substance or mixture and uses advised against

Identified uses

Veterinary vaccine.

Uses advised against

Not for human use

Supplier's details : Zoetis Canada Inc.

16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7

1-800-461-0917

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

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

Emergency telephone number (with hours of

operation)

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

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

Rocky Mountain Poison & Drug Safety: 1-866-531-8896 Product support/Technical services: 1-888-963-8471

Zoetis Inc. 10 Sylvan Way

Parsippany, New Jersey 07054 (USA)

Section 2. Hazard identification

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention: Observe good industrial hygiene practices.

Response : Wash hands after handling.

Storage : Store away from incompatible materials.

Disposal : Dispose of waste product or used containers according to local regulations.

Supplemental label

elements

: Avoid accidental injection.

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Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	Synonyms	% (w/w)	Identifiers
Infectious bursal disease virus	-	*	-
Gentamicin	-		CAS: 1403-66-3

^{*}Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Ranges if listed above for hazardous ingredient(s) are prescribed ranges. The actual concentration(s) or actual concentration range(s) are being withheld as a trade secret.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First-aid measures

Description of necessary first aid measures

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower

eyelids. Check for and remove any contact lenses. Get medical attention if irritation

occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and

shoes. Get medical attention if symptoms occur. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water.

Get medical attention immediately.

Ingestion : Wash out mouth with water. If material has been swallowed and the exposed

person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms

occur.

Most important symptoms/effects, acute and delayed

In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Coughing. Direct contact with eyes may cause temporary irritation. Mild skin irritation. Dusts may irritate the respiratory tract, skin and eyes. Exposure may cause temporary irritation, redness, or discomfort.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large

quantities have been ingested or inhaled.

Specific treatments: No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing : Use dry chemical powder.

media

Unsuitable extinguishing : None known.

media

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Section 5. Fire-fighting measures

Specific hazards arising from the chemical

: May form explosible dust-air mixture if dispersed.

Hazardous thermal decomposition products : No specific data.

Special protective actions for fire-fighters

: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 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. If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill

: Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill

ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Move containers from spill area. Use only non-sparking tools. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor.

Section 7. Handling and storage

Precautions for safe handling

Protective measures

: Put on appropriate personal protective equipment (see Section 8). Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Avoid accidental injection.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

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Section 7. Handling and storage

Conditions for safe storage, including any incompatibilities

: Store between the following temperatures: 2 to 7°C (35.6 to 44.6°F). Do not freeze. Prolonged exposure to higher temperatures may adversely affect potency. Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Biological exposure indices

No exposure indices known.

Control Banding Approach

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

Appropriate engineering controls

: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. 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.

Environmental exposure controls

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period.

Appropriate techniques should be used to remove potentially contaminated clothing.

Eye/face protection

: If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles.

Skin protection

Hand protection

: Wear appropriate chemical resistant gloves.

Body protection

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

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Section 8. Exposure controls/personal protection

Respiratory protection

: 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.

Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state : Solid. [Powder.]

Color Pale yellow to Reddish-white.

Odor Odorless. **Odor threshold** : Not available.

6 to 8

Melting point/freezing point : Not available. : Not available. **Boiling point or initial** boiling point and boiling

range

Flash point : Not applicable. : Not available. **Evaporation rate Flammability** Not available. Lower and upper explosion

limit/flammability limit

Not applicable.

Vapor pressure : Not available. Relative vapor density : Not applicable. Not available. Relative density Solubility in water : Not available. Partition coefficient: n-

octanol/water

Not applicable.

Auto-ignition temperature : Not applicable. **Decomposition temperature** : Not available.

Viscosity

Dynamic (room temperature): Not available. Kinematic (room temperature): Not available.

Kinematic (40°C (104°F)): Not available.

Particle characteristics

Pmax : Not available. Kst Not available. : Not available. **Min. Ignition Temperature**

(Dust)

Minimum ignition energy

(MIE) - dust cloud

Not available.

: Not available. Median particle size

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

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Section 10. Stability and reactivity

Conditions to avoid

: Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation. Do not freeze. Avoid exposure to light, sunlight and elevated temperatures. Prolonged exposure to higher temperatures may adversely affect potency.

Incompatible materials

: Reactive or incompatible with the following materials:

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

Remarks

: Reactive or incompatible with the following materials: oxidizing materials.

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name

Gentamicin Mouse - Intramuscular - LD50

oxidizing materials

167 mg/kg

Result

Rat - Intramuscular - LD50

463 mg/kg Rat - Oral - LD50 6600 mg/kg

Rat - Subcutaneous - LD50

710 mg/kg Rat - Oral - LD50 6600 mg/kg

Toxic effects: Behavioral - Tremor Behavioral - Convulsions or effect on seizure threshold Gastrointestinal - Other changes

Conclusion/Summary [Product]

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

Skin corrosion/irritation

Not available.

Conclusion/Summary [Product]

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

Serious eye damage/eye irritation

Product/ingredient name

Result Gentamicin Rabbit - Eyes - Not irritant

Conclusion/Summary [Product]

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

Respiratory corrosion/irritation

Not available.

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Section 11. Toxicological information

Conclusion/Summary [Product] : Due to partial or complete lack of data the classification is not possible.

Respiratory or skin sensitization

Not available.

Skin

Conclusion/Summary [Product] : Due to partial or complete lack of data the classification is not possible.

Respiratory

Conclusion/Summary [Product] : Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity (single exposure)

Not applicable.

Specific target organ toxicity (repeated exposure)

Not applicable.

Aspiration hazard

Not applicable.

Information on the likely routes of exposure

Not available.

Potential acute health effects

In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Coughing. Direct contact with eyes may cause temporary irritation. Mild skin irritation. Dusts may irritate the respiratory tract, skin and eyes. Exposure may cause temporary irritation, redness, or discomfort.

Potential chronic health effects

Not available.

General : Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.

Germ cell mutagenicity

Not available.

Conclusion/Summary [Product] : Due to partial or complete lack of data the classification is not possible.

Carcinogenicity

Not available.

Conclusion/Summary [Product]

Reproductive toxicity

Product/ingredient name Result

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

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Section 11. Toxicological information

Gentamicin Rat - Intramuscular

75 mg/kg [7 days per week]

Effects: LOAEL

Developmental: Positive

Conclusion/Summary [Product]

: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Gentamicin	6600	N/A	N/A	N/A	N/A

Other information

The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. In the event of accidental injection, an allergic reaction may occur.

Section 12. Ecological information

Toxicity

Not available.

Conclusion/Summary [Product]: No known significant effects or critical hazards. Avoid release to the

environment.

Persistence and degradability

Not available.

Conclusion/Summary [Product]: Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/Water partition : Not available.

coefficient

Other adverse effects

No known significant effects or critical hazards.

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Section 13. Disposal considerations

Disposal methods

: 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. The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	TDG Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

Canadian lists

Canadian NPRI : None of the components are listed. **CEPA Toxic substances** : None of the components are listed.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

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Section 15. Regulatory information

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : Not determined.
Canada : Not determined.
China : Not determined.

Eurasian Economic Union: Russian Federation inventory: Not determined.

Japan : Japan inventory (CSCL): Not determined.

Japan inventory (ISHL): Not determined.

New Zealand : Not determined. **Philippines** : Not determined. Republic of Korea : Not determined. **Taiwan** : Not determined. **Thailand** : Not determined. : Not determined. **Turkey United States** : Not determined. **Viet Nam** : Not determined.

Section 16. Other information

History

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Key to abbreviations : ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor DOT = Department of Transportation

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

HPR = Hazardous Products Regulations IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods IMO = International Maritime Organization

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships,

1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

N/A = Not available SGG = Segregation Group

TDG = Transportation of Dangerous Goods

UN = United Nations

Procedure used to derive the classification

Not classified.

References : Not available.

Notice to reader

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.

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