

SAFETY DATA SHEET



1. Identification

Product identifier	POULVAC BURSA F
Other means of identification	
Synonyms	POULVAC® BURSA F * BURSAL DISEASE LV (V877) * Bursavac * Infectious Bursal Vaccine, Live Virus (V877 Strain) * Websters Infectious Bursal Disease Vaccine (Strain V877, Live Virus) * Bursal Disease Vaccine, Live Virus (V877)
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	productsupport.au@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 Allergic reactions are possible.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Gentamicin	1403-66-3	##
Infectious bursal disease virus	Not assigned	
Neomycin Sulfate	1405-10-3	##

Nystatin	1400-61-9	##
Sucrose	57-50-1	

Composition comments ## Trace

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	Wash off with soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
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 IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Allergic reactions are possible. 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 Provide general supportive measures and 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 Use water spray to cool unopened containers.

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. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Avoid contact with eyes, skin, and clothing. Avoid inhalation of vapour, fumes, dust and/or mist from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

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

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. 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 in original containers for re-use.

7. Handling and storage

Precautions for safe handling

Ensure adequate ventilation. Wear appropriate personal protective equipment. Avoid contact with eyes, skin, and clothing. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged exposure. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wash contaminated clothing before reuse. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store in a closed container away from incompatible materials.

8. Exposure controls and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components

Type

Value

Neomycin Sulfate (CAS 1405-10-3)

TWA

100 µg/m3

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

Components

Type

Value

Form

Sucrose (CAS 57-50-1)

TWA

10 mg/m3

Inhalable dust.

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

Components

Type

Value

Form

Sucrose (CAS 57-50-1)

TWA

10 mg/m3

Inspirable dust.

US. ACGIH Threshold Limit Values

Components

Type

Value

Sucrose (CAS 57-50-1)

TWA

10 mg/m3

UK. EH40 Workplace Exposure Limits (WELs)

Components

Type

Value

Sucrose (CAS 57-50-1)

STEL

20 mg/m3

TWA

10 mg/m3

Biological limit values

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

Exposure guidelines

OEL Additional Information: Neomycin sulfate - Sensitizer

Control banding approach

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

Nystatin: Zoetis OEB 3 (control exposure to the range of 10ug/m3 to < 100ug/m3)

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

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 appropriate chemical resistant gloves.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.
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 Freeze-dried preparation.

Physical state Solid.

Form Solid.

Colour Not available.

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 Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

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. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on possible routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Prolonged skin contact may cause temporary irritation.
 Neomycin Sulfate Species: Rabbit
 Severity: Moderate

Eye contact Direct contact with eyes may cause temporary irritation.
 Neomycin Sulfate Species: Rabbit
 Severity: Minimal

Gentamicin Species: Rabbit
 Severity: Non-irritating

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to exposure Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Allergic reactions are possible. 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 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
Neomycin Sulfate (CAS 1405-10-3)		
Acute		
Intraperitoneal		
LD50	Mouse	116 mg/kg
Oral		
LD50	Mouse	2880 mg/kg
	Rat	2750 mg/kg
Subcutaneous		
LD50	Mouse	275 mg/kg
	Rat	633 mg/kg
Chronic		
Oral		
NOAEL	Cat	12 mg/kg/day, 12 months (Target organ(s): Blood forming organs)
	Rat	25 mg/kg/day, 2 years (Not carcinogenic)
Subacute		
Oral		
NOAEL	Dog	100 mg/kg/day, 6 weeks (No effects at maximum dose)

Components	Species	Test Results
<u>Subchronic</u>		
Oral		
NOAEL	Guinea Pig	10 mg/kg/day, 3 months (No effects at maximum dose)
Subcutaneous		
LOAEL	Dog	20 mg/kg/day, 3 months (Target organ(s): Kidney)
	Guinea Pig	10 mg/kg/day, 3 months (Target organ(s): Kidney)
Nystatin (CAS 1400-61-9)		
<u>Acute</u>		
Oral		
LD50	Rat	10000 mg/kg
Sucrose (CAS 57-50-1)		
<u>Acute</u>		
Oral		
LD50	Rat	29700 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Neomycin Sulfate	Species: Rabbit Severity: Moderate	
Serious eye damage/irritation	Direct contact with eyes may cause temporary irritation.	
Eye contact		
Neomycin Sulfate	Species: Rabbit Severity: Minimal	
Gentamicin	Species: Rabbit Severity: Non-irritating	
Respiratory or skin sensitisation		
Respiratory sensitisation	Based on available data, the classification criteria are not met. Allergic reactions are possible.	
Skin sensitisation	Based on available data, the classification criteria are not met. Allergic reactions are possible.	
Skin sensitisation		
Neomycin Sulfate	Severity: positive	
Germ cell mutagenicity	Due to partial or complete lack of data the classification is not possible. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Neomycin Sulfate	Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella , E. coli	
Sucrose	Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella	
Neomycin Sulfate	In Vitro Chromosome Aberration Result: positive Species: Human lymphocytes	
	In Vivo Cytogenetics Result: negative Species: Mouse	
	Mammalian Cell Mutagenicity Result: negative Species: Chinese Hamster Ovary (CHO) cells	

Carcinogenicity	Due to partial or complete lack of data the classification is not possible.
ACGIH Carcinogens	
Sucrose (CAS 57-50-1)	A4 Not classifiable as a human carcinogen.
Reproductive toxicity	Due to partial or complete lack of data the classification is not possible.
Developmental effects	
Neomycin Sulfate	6 mg/kg/day Prenatal & Postnatal Development, Developmental toxicity Result: LOAEL Species: Rat Organ: Subcutaneous
Gentamicin	75 mg/kg/day Embryo / Fetal Development, Developmental toxicity Result: LOAEL Species: Rat Organ: Intramuscular
Reproductivity	
Neomycin Sulfate	25 mg/kg/day 2 Gen Reproductive Toxicity, Fetotoxicity Result: NOAEL Species: Rat Organ: Oral
	25 mg/kg/day Reproductive & Fertility, No effects at maximum dose Result: NOAEL Species: Rat Organ: Oral
	4000 mg/l Reproductive & Fertility, No effects at maximum dose Result: NOAEL Species: Mouse Organ: Oral
Specific target organ toxicity - single exposure	Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Due to partial or complete lack of data the classification is not possible.
Aspiration hazard	Not an aspiration hazard.
Other information	The antigens included in this product are non-infectious. All have been prepared from attenuated preparations of microorganisms.

12. Ecological information

Ecotoxicity Based on available data, the classification criteria are not met for hazardous to the aquatic 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. Avoid release to the environment.

Components	Species	Test Results
Neomycin Sulfate (CAS 1405-10-3)	EC50 Activated sludge	399 mg/l
	NOEC Salmo gairdneri (Trout)	> 1000 mg/l, 96 Hours
Aquatic		
Crustacea	EC50 Daphnia magna (Water Flea)	68 mg/l, 48 Hours
Persistence and degradability	No data available for this product.	
Bioaccumulative potential	No data available for this product.	
Partition coefficient n-octanol / water (log Kow)		
Neomycin Sulfate	1.2, Log D, predicted, pH 7.4	

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 contaminate ponds, waterways or ditches with chemical or used container. Do not dispose of waste into sewer. 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 applicable.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals.

APVMA approval number: 46011

This SDS replaces version: Issued September 2014

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Schedule 3

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Schedule 4

Gentamicin (CAS 1403-66-3)

Nystatin (CAS 1400-61-9)

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

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

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

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

Not applicable.

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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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	29-August-2019
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 Physical & Chemical Properties: Multiple Properties GHS: Classification