

SAFETY DATA SHEET



1. Identification

Product identifier Special Formula 17900 Forte-V Lactating Intramammary Antibiotic Suspension (APVMA No. 38696)

Other means of identification None.

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product used as antibiotic agent

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 australia.animalhealth@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 Skin corrosion/irritation Category 2
 Sensitization, respiratory Category 1
 Sensitization, skin Category 1
 Reproductive toxicity (the unborn child) Category 1A

Environmental hazards Not classified.

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard

Signal word Danger

Hazard Statement(s) Causes skin irritation. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May damage the unborn child.

Precautionary Statement(s)

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing mist or vapour. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Use personal protective equipment as required. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.

Response IF exposed or concerned: Get medical advice/attention. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.

Storage Store locked up.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards which do not result in classification	None known.
Supplemental information	May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe. Common adverse reactions associated with the clinical use of streptomycin include vestibular ototoxicity (nausea, vomiting, and vertigo); parasthesia of face; rash; fever; urticaria; angioneurotic edema; and eosinophilia. Streptomycin can cause fetal harm (ototoxicity) when administered to a pregnant woman. Clinical use may cause Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis).

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Peanut Oil	8002-03-7	>60
Dihydrostreptomycin sulfate	1425-61-2	≤ 2
Neomycin sulfate	1405-10-3	≤ 2
Novobiocin Sodium	1476-53-5	≤ 2

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. Call a physician if symptoms develop or persist.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation develops and persists. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell. Rinse mouth. Get medical attention if symptoms occur. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Personal protection for first-aid responders	For personal protection, see section 8 of the SDS. 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. Wash contaminated clothing before reuse.
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Symptoms caused by exposure	Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Difficulty in breathing. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash.
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Medical attention and special treatment	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
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5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
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.
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Special protective equipment and precautions for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
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Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
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Hazchem Code	None.
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General fire hazards	No unusual fire or explosion hazards noted.
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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 Ensure adequate ventilation. Keep unnecessary personnel away. Do not breathe mist or vapour. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Use personal protection recommended in Section 8 of the SDS. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Ventilate the contaminated area. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas.

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.

7. Handling and storage

Precautions for safe handling Do not handle until all safety precautions have been read and understood. Use only with adequate ventilation. Wear personal protective equipment. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Observe good industrial hygiene practices. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight.

Conditions for safe storage, including any incompatibilities Store locked up. Keep away from heat, sparks and open flame. Store away from direct sunlight. Keep tightly closed in a dry, cool and well-ventilated place. @ 15-30°C (59-86°F). Store away from incompatible materials (see Section 10 of the SDS). Keep away from food, drink and animal feeding stuffs. Keep out of the reach of children.

8. Exposure controls and personal protection

Control parameters

Occupational exposure limits

Zoetis

Components	Type	Value
Neomycin sulfate (CAS 1405-10-3)	TWA	100 µg/m ³
Novobiocin Sodium (CAS 1476-53-5)	TWA	250 µg/m ³

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

Components	Type	Value	Form
Peanut Oil (CAS 8002-03-7)	TWA	10 mg/m ³	Inhalable mist.

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

Components	Type	Value	Form
Peanut Oil (CAS 8002-03-7)	TWA	10 mg/m ³	Inspirable dust.

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

Exposure guidelines OEL Additional Information: Sensitizer

Control banding approach Dihydrostreptomycin sulfate: Zoetis OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Appropriate engineering controls	Ensure adequate ventilation, especially in confined areas. 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. Eye wash facilities and emergency shower must be available when handling this product.
Individual protection measures, for example personal protective equipment (PPE)	
Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.
Other	Wear appropriate chemical resistant clothing.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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. 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. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.
Thermal hazards	Not applicable.
Hygiene measures	Observe any medical surveillance requirements. 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Oily liquid
Colour	Not available.
Odour	Mild.
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 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 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 Heat, flames and sparks. Sunlight. Contact with incompatible materials. Avoid high temperatures.

Incompatible materials Strong oxidising agents. Acids. Alkalies.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation may be harmful.

Skin contact Causes skin irritation. May cause an allergic skin reaction.

Neomycin sulfate Species: Rabbit
Severity: Moderate

Peanut Oil Species: Rabbit
Severity: Moderate

Eye contact Direct contact with eyes may cause temporary irritation.

Neomycin sulfate Species: Rabbit
Severity: Minimal

Novobiocin Sodium Species: Rabbit
Severity: Moderate

Ingestion Expected to be a low ingestion hazard.

Symptoms related to exposure Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Difficulty in breathing. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash.

Acute toxicity May cause an allergic skin reaction.

Components	Species	Test results
Dihydrostreptomycin sulfate (CAS 1425-61-2)		
Acute		
Intraperitoneal		
LD50	Mouse	1380 mg/kg
Intravenous		
LD50	Rat	137 mg/kg
Oral		
LD50	Mouse	> 600 mg/kg
Subcutaneous		
LD50	Rat	1100 mg/kg
Subchronic		
Intramuscular		
LOEL	Monkey	9375 mg/kg/day, 75 days (Target organ(s): None identified)

Components	Species	Test results
Neomycin sulfate (CAS 1405-10-3)		
<u>Acute</u>		
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
<u>Chronic</u>		
Oral		
NOAEL	Cat	12 mg/kg/day, 12 months (Target organ(s): Blood forming organs)
	Rat	25 mg/kg/day, 2 years (Not carcinogenic)
<u>Subacute</u>		
Oral		
NOAEL	Dog	100 mg/kg/day, 6 weeks (No effects at maximum dose)
<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)
Novobiocin Sodium (CAS 1476-53-5)		
<u>Acute</u>		
Intraperitoneal		
LD50	Mouse	225 mg/kg
	Rat	370 mg/kg
Oral		
LD50	Mouse	962 mg/kg
	Rat	3200 mg/kg
Other		
LD50	Rat	360 mg/kg (Para-periosteal)
Skin corrosion/irritation	Causes skin 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	
Novobiocin Sodium	Species: Rabbit Severity: Moderate	
Respiratory or skin sensitisation		
Respiratory sensitisation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	

Skin sensitisation May cause an allergic skin reaction.

Skin sensitisation

Neomycin sulfate	Severity: positive
Dihydrostreptomycin sulfate	Severity: Sensitiser
Novobiocin Sodium	Severity: Sensitiser

Germ cell mutagenicity 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
Peanut Oil	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.

Reproductive toxicity May damage the unborn child.

Developmental effects

Novobiocin Sodium	40 mg/kg/day Embryo / Fetal Development, Not teratogenic Result: NOAEL Species: Rat Organ: Oral
Neomycin sulfate	6 mg/kg/day Prenatal & Postnatal Development, Developmental toxicity Result: LOAEL Species: Rat Organ: Subcutaneous

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
Novobiocin Sodium	40 mg/kg/day Reproductive & Fertility, No effects at maximum dose Result: NOAEL Species: Rat Organ: Oral

Reproductivity
Neomycin sulfate

4000 mg/l Reproductive & Fertility, No effects at maximum dose
Result: NOAEL
Species: Mouse
Organ: Oral

Dihydrostreptomycin sulfate

7500 mg/kg/day Reproductive & Fertility, Developmental toxicity
Result: LOEL
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.

Chronic effects Prolonged inhalation may be harmful.

Other information May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe. Common adverse reactions associated with the clinical use of streptomycin include vestibular ototoxicity (nausea, vomiting, and vertigo); parasthesia of face; rash; fever; urticaria; angioneurotic edema; and eosinophilia. Streptomycin can cause fetal harm (ototoxicity) when administered to a pregnant woman. Clinical use may cause Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis).

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
Neomycin sulfate (CAS 1405-10-3)	EC50	Activated sludge 399 mg/l
		Daphnia magna (Water Flea) 68 mg/l, 48 Hours
	NOEC	Salmo gairdneri (Trout) > 1000 mg/l, 96 Hours

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

Bioaccumulative potential

**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 allow this material to drain into sewers/water supplies. 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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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 established.

15. Regulatory information

Safety, health and environmental regulations

National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No: 38696

Poison Schedule (Product) - Schedule 4

This SDS replaces version: Issued 24 August 2015

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

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
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	Yes
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	01-December-2016
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