

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Amiglyde-V Veterinary Injection</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Amiglyde-V * Amikacin sulfate injection
<b>Recommended use</b>	Veterinary antibiotic agent
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (USA)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300  International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (CA)</b>	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	productsupport@zoetis.com
<b>Product Support</b>	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

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
<b>Environmental hazards</b>	Not classified.	

### Label elements



<b>Signal word</b>	Danger
<b>Hazard statement</b>	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>Precautionary statement</b>	
<b>Prevention</b>	Avoid breathing mist or vapour. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.
<b>Response</b>	IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE/doctor. Take off contaminated clothing and wash it before reuse.

<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Other hazards</b>	None known.
<b>Supplemental information</b>	Aminoglycoside. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Sodium Citrate		6132-04-3	2.5
Sodium bisulfite		7631-90-5	0.66
Benzethonium chloride		121-54-0	0.01
Amikacin Sulfate		37517-28-5	50 or 250 mg/ml
Water for Injection		7732-18-5	

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

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist. If breathing is difficult, trained personnel should give oxygen.
<b>Skin contact</b>	Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.
<b>Eye contact</b>	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
<b>Most important symptoms/effects, acute and delayed</b>	Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
<b>General information</b>	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. Wash contaminated clothing before reuse.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Ventilate closed spaces before entering them. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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**Methods and materials for containment and cleaning up**

Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area). Ensure adequate ventilation. Prevent product from entering drains. 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.

**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.

**7. Handling and storage****Precautions for safe handling**

Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Observe good industrial hygiene practices. Provide adequate ventilation. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Avoid accidental injection. Avoid release to the environment. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Wash contaminated clothing before reuse.

**Conditions for safe storage, including any incompatibilities**

Store locked up. Store in a well-ventilated place. Protect from sunlight. Keep away from heat, sparks and open flame. @ 15-30°C (59-86°F). Do not freeze. Keep away from food, drink and animal feeding stuffs. Store away from incompatible materials (see Section 10 of the SDS).

**8. Exposure controls/personal protection****Occupational exposure limits****US. ACGIH Threshold Limit Values**

Components	Type	Value
Sodium Bisulfite (CAS 7631-90-5)	TWA	5 mg/m <sup>3</sup>

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

Components	Type	Value
Sodium Bisulfite (CAS 7631-90-5)	TWA	5 mg/m <sup>3</sup>

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

Components	Type	Value
Sodium Bisulfite (CAS 7631-90-5)	TWA	5 mg/m <sup>3</sup>

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

Components	Type	Value
Sodium Bisulfite (CAS 7631-90-5)	TWA	5 mg/m <sup>3</sup>

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

Components	Type	Value
Sodium Bisulfite (CAS 7631-90-5)	TWA	5 mg/m <sup>3</sup>

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

Components	Type	Value
Sodium Bisulfite (CAS 7631-90-5)	TWA	5 mg/m <sup>3</sup>

**Biological limit values**

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

**Control banding approach**

Amikacin Sulfate: Zoetis OEB 2 (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

<b>Appropriate engineering controls</b>	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.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves.
<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	Clear, colorless to pale yellow

**Odour** Slight.

**Odour threshold** Not available.

**pH** 4.6

**Melting point/freezing point** 0 °C (32 °F)

**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)** Soluble

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidising agents. Acids. Bases. organic materials.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation may be harmful.	
<b>Skin contact</b>	May cause an allergic skin reaction.	
Benzethonium chloride	Species: Rabbit	Severity: Mild
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.	
Benzethonium chloride	Species: Rabbit	Severity: Severe
<b>Ingestion</b>	Expected to be a low ingestion hazard.	

**Symptoms related to the physical, chemical and toxicological characteristics**      Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash.

### Information on toxicological effects

**Acute toxicity**      Allergic reactions are possible.

Components	Species	Test results
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Benzethonium chloride (CAS 121-54-0)

#### Acute

#### **Intravenous**

LD50	Rat	19 mg/kg
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#### **Oral**

LD50	Rat	368 mg/kg
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#### **Subcutaneous**

LD50	Rat	119 mg/kg
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Sodium bisulfite (CAS 7631-90-5)

#### Acute

#### **Oral**

LD50	Rat	2 g/kg
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**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**

Benzethonium chloride	Species: Rabbit	Severity: Severe
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## Respiratory or skin sensitisation

### Canada - Alberta OELs: Irritant

Sodium bisulfite (CAS 7631-90-5) Irritant

**Respiratory sensitisation** May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Skin sensitisation** May cause an allergic skin reaction.

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

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

### ACGIH Carcinogens

Sodium bisulfite (CAS 7631-90-5) A4 Not classifiable as a human carcinogen.

### Canada - Manitoba OELs: carcinogenicity

Sodium bisulfite (CAS 7631-90-5) Not classifiable as a human carcinogen.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Sodium bisulfite (CAS 7631-90-5) 3 Not classifiable as to carcinogenicity to humans.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects. Due to partial or complete lack of data the classification is not possible. Possible risk of harm to the unborn child.

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - repeated exposure** Due to partial or complete lack of data the classification is not possible. This product may affect Auditory organs. Kidneys. through prolonged or repeated exposure.

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** Prolonged inhalation may be harmful.

**Further information** Caution - Pharmaceutical agent. Aminoglycoside. Occupational exposure to the substance or mixture may cause adverse effects.

## 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
Benzethonium chloride (CAS 121-54-0)			
<b>Aquatic</b>			
Fish	LC50	Bluegill ( <i>Lepomis macrochirus</i> )	1.4 mg/l, 96 hours
Sodium bisulfite (CAS 7631-90-5)			
<b>Aquatic</b>			
Fish	LC50	Western mosquitofish ( <i>Gambusia affinis</i> )	240 mg/l, 96 hours
Sodium Citrate (CAS 6132-04-3)			
<b>Aquatic</b>			
Crustacea	EC50	Water flea ( <i>Ceriodaphnia dubia</i> )	655 - 825.9 mg/l, 48 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. The product is soluble in water.

**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. Do not contaminate ponds, waterways or ditches with chemical or used container. 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.

<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>TDG</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not established.

## 15. Regulatory information

<b>Canadian regulations</b>	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.
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### 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.

### 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)	Yes
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 (PICCS)	No

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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** 03-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  
Physical & Chemical Properties: Multiple Properties