

SAFETY DATA SHEET



Revision date: 14-Jan-2014

Version: 2.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Resvac® BRSV

Trade Name: Resvac® BRSV
Synonyms: Bovine Respiratory Syncytial Virus - Modified Live Virus
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary Vaccine

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

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

2. HAZARDS IDENTIFICATION

Appearance: Lyophilized powder
Classification of the Substance or Mixture
GHS - Classification Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Short Term: Toxicity following ingestion is not expected. Ingestion should be avoided. In the event of accidental injection, an allergic reaction may occur.
Long Term: Repeated exposure to dust or mist may produce allergic reactions.
Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Neomycin Sulfate	1405-10-3	215-773-1	Xn;R42/43 Repr.Cat.3;R63	Resp. Sens. 1 (H334) Skin Sens.1(H317) Repro. 2 (H361) Aq. Acute 3 (H402) Aq. Chronic 3 (H412)	<0.1
Polymyxin B	1404-26-8	215-768-4	Xn;R22 Xn;R42/43	Acute Tox. 4 (H302) Skin Sens. 1 (H317) Resp Sens. 1 (H334)	<0.1
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Short chain peptide	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Appropriate cell substrates	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Bovine Respiratory Syncytial Virus	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. If discomfort persists, get medical attention.

Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** None known

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Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Toxic or corrosive gases are expected in fires involving this mixture.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Keep away from heat, sparks, and flame. Avoid breathing dust. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. Avoid accidental injection.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

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

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Neomycin Sulfate

Zoetis OEL TWA 8-hr

100µg/m³ Sensitizer

Sucrose

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Polymyxin B

Zoetis OEB

OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Wear impervious gloves if skin contact is possible.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Wear protective clothing with long sleeves to avoid routine skin contact. Wash hands and arms thoroughly after handling this material. Clean up spills immediately.

Respiratory protection:

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Lyophilized powder
Odor: No data available.
Molecular Formula: Mixture

Color: No data available.
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Soluble: Water (based on components)
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
No data available

Neomycin Sulfate

Predicted 7.4 Log D 1.20

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9. PHYSICAL AND CHEMICAL PROPERTIES

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur .

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.

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

Hazardous Decomposition Products: None expected under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been fully investigated. The antigens included in this product are non-infectious. All have been prepared from modified or inactivated preparations of microorganisms. The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Polymyxin B

Mouse Oral LD50 790 mg/kg
Mouse Para-periosteal LD50 3980ug/kg
Rat Subcutaneous LD50 50mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

Neomycin Sulfate

Rat Oral LD 50 2750 mg/kg
Mouse Oral LD 50 2880mg/kg
Mouse Intraperitoneal LD 50 116mg/kg

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11. TOXICOLOGICAL INFORMATION

Rat Subcutaneous LD 50 633mg/kg
Mouse Subcutaneous LD 50 275mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Neomycin Sulfate

Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Minimal
Skin Sensitization Positive

Skin Irritation / Sensitization

Sensitization (allergic skin reaction) may occur, based on effects of individual components. Not determined for this mixture. Irritation is not expected to occur based on the effects of individual components.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Neomycin Sulfate

6 Week(s) Dog Oral 100 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Guinea Pig Oral 10 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Dog Subcutaneous 20 mg/kg/day LOAEL Kidney
12 Month(s) Cat Oral 12 mg/kg/day NOAEL Blood forming organs
3 Month(s) Guinea Pig Subcutaneous 10 mg/kg/day LOAEL Kidney

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Neomycin Sulfate

Reproductive & Fertility Mouse Oral 4000 mg/L NOAEL No effects at maximum dose
2 Generation Reproductive Toxicity Rat Oral 25 mg/kg/day NOAEL Fetotoxicity
Reproductive & Fertility Rat Oral 25 mg/kg/day NOAEL No effects at maximum dose
Prenatal & Postnatal Development Rat Subcutaneous 6 mg/kg/day LOAEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Polymyxin B

In Vitro Negative
In Vivo Negative

Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Neomycin Sulfate

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
In Vivo Cytogenetics Mouse Negative
In Vitro Chromosome Aberration Human Lymphocytes Positive

Mutagenicity Not determined for this mixture.

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Neomycin Sulfate

2 Year(s) Rat Oral 25 mg/kg/day NOAEL Not carcinogenic

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11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Additional Information: This mixture contains a modified live virus vaccine for use in cattle.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Neomycin Sulfate

Daphnia magna (Water Flea) OECD EC50 48 Hours 68 mg/L
Salmo gairdneri (Trout) OECD NOEC 96 Hours >1000 mg/L

Neomycin Sulfate

Activated sludge OECD EC50 399 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Neomycin Sulfate

Predicted 7.4 Log D 1.20

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

Neomycin Sulfate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity initial date 10/1/92 internal use
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-773-1

Polymyxin B

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	215-768-4

Short chain peptide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Appropriate cell substrates

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

Bovine Respiratory Syncytial Virus

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Gelatin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-554-6

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15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
H361 - Suspected of damaging fertility or the unborn child
H402 - Harmful to aquatic life
H412 - Harmful to aquatic life with long lasting effects
H302 - Harmful if swallowed

R63 - Possible risk of harm to the unborn child.
R22 - Harmful if swallowed.
R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material 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.

End of Safety Data Sheet