

Safety Data Sheet

RabAvert Rabies Vaccine

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name: RabAvert Rabies Vaccine

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

Recommended uses: Medicinal product.

1.3. Details of the supplier of the safety data sheet

Supplier

Company: Bavarian Nordic, Inc.
 Address: 3025 Carrington Mill Boulevard.
 Zip code: 27560
 City: Morrisville, NC
 Country: UNITED STATES OF AMERICA
 E-mail: info@bavarian-nordic.com
 Phone: +1 984-243-5000 (direct office)

1.4. Emergency Telephone Number

+1 984-243-5000 (Bavarian Nordic, Inc.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

HazCom classification: The product shall not be classified as hazardous according to the classification and labeling rules for substance and mixtures.

Most serious harmful effects: May cause slight irritation to the skin and eyes.

2.2. Label elements

The product shall not be classified as hazardous according to the classification and labeling rules for substance and mixtures.

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Substance	CAS No./ EC No./ REACH Reg. No.	Concentration	Notes
Inactivated Rabies virus		2.5IU	
2-amino-2-(hydroxymethyl)propane-1,3-diol hydrochloride	1185-53-1 214-684-5	4 - 6%	
Disodium dihydrogen ethylenediaminetetraacetate	139-33-3	< 1%	
Heamaccel (Polygeline)		< 20%	
chlortetracycline-	57-62-5	Trace	

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Neomycin sulphate	1405-10-3 215-773-1	Trace	
Amphotericin	1397-89-3 215-742-2	Trace	

Ingredient comments: Unit for "Inactivated Rabies virus" is IU (International Units)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:	Seek fresh air.
Ingestion:	Wash out mouth thoroughly and drink 1-2 glasses of water in small sips. Seek medical advice in case of persistent discomfort.
Skin contact:	Remove contaminated clothing. Wash skin with soap and water.
Eye contact:	Flush with water (preferably using eye wash equipment) until irritation subsides. Seek medical advice if symptoms persist.
General:	Bring the safety data sheet or label when seeking medical advice.

4.2. Most important symptoms and effects, both acute and delayed

May cause slight irritation to the skin and eyes.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptoms. No special immediate treatment required.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:	Extinguish with powder, foam or water mist. Use water or water mist to cool non-ignited stock.
Unsuitable extinguishing media:	Do not use a jet of water, as it may spread the fire.

5.2. Special hazards arising from the substance or mixture

Product decomposes in fire conditions or when heated to high temperatures, and inflammable and toxic gases may be released. Carbon monoxide and carbon dioxide.

5.3. Advice for firefighters

Move containers from danger area if it can be done without risk. Avoid inhalation of vapor and smoke gases - seek fresh air. Wear Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Stop leak if this can be done without risk. Stay upwind/keep distance from source.

For emergency responders: In addition to the above: Normal protective clothing is recommended.

6.2. Environmental precautions

Prevent spillage from entering drains and/or surface water.

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6.3. Methods and material for containment and cleaning up

Contain and absorb spills using sand or other absorbent material and transfer to suitable waste containers. Wipe up minor spills with a cloth.

6.4. Reference to other sections

See section 8 for type of protective equipment. See section 13 for instructions on disposal.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Running water and eye wash equipment should be available. Wash hands before breaks, before using restroom facilities, and at the end of work.

7.2. Conditions for safe storage, including any incompatibilities

Keep in tightly closed original packaging. Storage temperature: 36 - 46 °F. Store frost-free. Do not store with the following: Strong oxidisers. Avoid direct sunlight.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit: Contains no substances subject to reporting requirements

Measuring methods: Compliance with occupational exposure limits may be checked by occupational hygiene measurements.

Legal basis: ACGIH Threshold Limit Values (TLV's) and Biological Exposure Indices (BEI's), 2021. OSHA 29 CFR part 1910.1000, table Z1-Z3, Limits for Air Contaminants 2006.

8.2. Exposure controls

Appropriate engineering controls: Wear the personal protective equipment specified below.

Personal protective equipment, eye/face protection: Wear safety goggles if there is a risk of eye splash.

Personal protective equipment, skin protection: Wear suitable protective clothing.

Personal protective equipment, hand protection: Use disposable gloves of nitrile rubber. The suitability and durability of a glove is dependant on usage, e.g. frequency and duration of contact, glove material thickness, functionality and chemical resistance. Always seek advice from the glove supplier.

Personal protective equipment, respiratory protection: Not required.

Environmental exposure controls: Ensure compliance with local regulations for emissions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties



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Parameter	Value/unit
State	Powder
Colour	White
Odour	Odorless
Solubility	No data

Parameter	Value/unit	Remarks
Odour threshold	No data	
Melting point	0 °C	
Freezing point	No data	
Initial boiling point and boiling range	100 °C	
Flammability (solid, gas)	No data	
Flammability limits	No data	
Explosion limits	No data	
Flash Point	No data	
Auto-ignition temperature	No data	
Decomposition temperature	No data	
pH (solution for use)	No data	
pH (concentrate)	No data	
Kinematic viscosity	No data	
Viscosity	No data	
Partition coefficient n-octanol/water	No data	
Vapour pressure	No data	
Density	No data	
Relative density	~ 1	
Vapour density	No data	
Relative density (sat. air)	No data	
Particle characteristics	No data	

9.2. Other information

Other Information: None.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reacts with the following: Strong oxidisers.

10.2. Chemical stability

The product is stable when used in accordance with the supplier's directions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Avoid temperatures <32°F.

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10.5. Incompatible materials

Strong oxidisers.

10.6. Hazardous decomposition products

None known. The product decomposes when combusted or heated to high temperatures and the following toxic gases can be formed: Carbon monoxide and carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity - oral:	Ingestion may cause discomfort. The product does not have to be classified. Test data are not available.
Acute toxicity - dermal:	The product does not have to be classified. Test data are not available.
Acute toxicity - inhalation:	The product does not have to be classified. Test data are not available.
Skin corrosion/irritation:	May cause slight irritation. The product does not have to be classified. Test data are not available.
Serious eye damage/eye irritation:	Temporary irritation. The product does not have to be classified. Test data are not available.
Respiratory sensitisation or skin sensitisation:	The product does not have to be classified. Test data are not available.
Germ cell mutagenicity:	The product does not have to be classified. Test data are not available.
Carcinogenic properties:	The product does not have to be classified. Test data are not available.
Reproductive toxicity:	The product does not have to be classified. Test data are not available.
Single STOT exposure:	The product does not have to be classified. Test data are not available.
Repeated STOT exposure:	The product does not have to be classified. Test data are not available.
Aspiration hazard:	The product does not have to be classified. Test data are not available.

11.2. Information on other hazards

Other toxicological effects: None known.

SECTION 12: Ecological information

12.1. Toxicity

The product does not have to be classified. Test data are not available.

12.2. Persistence and degradability

Test data are not available.

12.3. Bioaccumulative potential

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Test data are not available.

12.4. Mobility in soil

Test data are not available.

12.5. Results of PBT and vPvB assessment

The product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

None known.

12.7. Other adverse effects

None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Avoid discharge to drain or surface water.

If this product as supplied becomes a waste, it does not meet the criteria of a hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261.

Empty, cleansed packaging should be disposed of for recycling.

Uncleansed packaging is to be disposed of via the local waste-removal scheme.

Category of waste:

SECTION 14: Transport information

14.1. UN number or ID number: Not applicable.

14.4. Packing group: Not applicable.

14.2. UN proper shipping name: Not applicable.

14.5. Environmental hazards: Not applicable.

14.3. Transport hazard class(es): Not applicable.

14.6. Special precautions for user

None.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Special Provisions: None.

Proposition 65

Chemicals known to cause cancer: None listed.

Chemicals known to cause reproductive toxicity: None listed.

SARA

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Section 302: None listed.

Section 313: None listed.

Section 311/312: Not included

15.2. Chemical Safety Assessment

Other Information: Chemical safety assessment has not been performed.

SECTION 16: Other information

Version history and indication of changes

Version	Revision date	Responsible	Changes
1.0.0	7/30/2021	Bureau Veritas HSE / MPE	

Abbreviations: PBT: Persistent, Bioaccumulative and Toxic
vPvB: Very Persistent and Very Bioaccumulative
STOT: Specific Target Organ Toxicity

Other Information: This safety data sheet has been prepared for and applies to this product only. It is based on our current knowledge and the information that the supplier was able to provide about the product at the time of preparation. The safety data sheet complies with applicable law on preparation of safety data sheets in accordance with CFR29, §1910.1200.

Training advice: A thorough knowledge of this safety data sheet should be a prerequisite condition.

Issued: 7/30/2021

Classification method: Calculation based on the hazards of the known components.

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