

Product Name: Vaxsafe® RIS Vaccine (living)

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Version 7, issued: November, 2021

Section 1 - Identification of The Material and Supplier

Bioproperties Pty Ltd Phone: 03 9871 2000 (office hours)

36 Charter St Fax: 03 9876 0556

Ringwood, Vic 3134 Emergency 0417 548 879 (any time)

Chemical nature: The active ingredient consists of an avian herpes virus in a protective buffer.

Trade Name: Vaxsafe® RIS Vaccine (living)

APVMA Code: 50485

Product Use: A vaccine to control Marek's Disease in chickens.

Creation Date: August, 2004

This version issued: November, 2021 and is valid for 5 years from this date. Poisons Information Centre: Phone 13 11 26 from anywhere in Australia

Section 2 - Hazards Identification

Statement of Hazardous Nature

This product is classified as: Not classified as hazardous according to the criteria of SWA.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

SUSMP Classification: None allocated.

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG)

Code, IATA or IMDG/IMSBC criteria. **UN Number:** None allocated.

GHS Signal word: NONE. Not hazardous.

PREVENTION

P102: Keep out of reach of children.

P262: Do not get in eyes, on skin, or on clothing.

P281: Use personal protective equipment as required.

RESPONSE

P353: Rinse skin or shower with water.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P370+P378: Not combustible. Use extinguishing media suited to burning materials.

STORAGE

P411: Store in liquid nitrogen.

DISPOSAL

P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Emergency Overview

Physical Description & Colour: Frozen, pale pink or straw-coloured liquid in a labelled, sealed, clear glass ampoule stored in liquid nitrogen.

Odour: No odour data.

Major Health Hazards: No significant risk factors have been found for this product.

Note: This product is stored in liquid nitrogen which can cause frostbite and replace air in enclosed spaces. Before working with the vaccine it is important to become fully familiar with the safe use and handling of liquid nitrogen – see AS 1894 - 1976 Code of practice for the safe handling of Cryogenic Fluids, and study its SDS.

Section 3 - Composition/Information on Ingredients				
Ingredients	CAS No	Conc. (%)	TWA (mg/m ³)	STEL (mg/m ³)
Biological culture substrates*	not set	96.25	not set	not set
Dimethyl sulfoxide (DMSO)	67-68-5	3.75	not set	not set

^{*} Mareks disease virus, Rispens Strain, living, in Specific Pathogen Free (SPF) chicken embryo cells suspended in a buffer of ingredients determined not to be hazardous (including animal tissue components).

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

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Section 4 - First Aid Measures

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 11 26 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Inhalation: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Skin Contact: Gently brush away excess material. Irritation is unlikely. However, if irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

Eye Contact: Quickly and gently wipe material from eyes. No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes. Take special care if exposed person is wearing contact lenses.

Ingestion: If product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

Injection: If accidental self-injection occurs, seek medical advice as soon as possible. Wash the wound under clean running water to remove any unabsorbed vaccine. Cover the wound with a band-aid, or suitable alternative, to stop any penetration of dirt. Inflammation of the area may occur. Seek medical or paramedical advice as to the extent and management of the tissue damaged, bring this SDS with you. Check your tetanus immunisation status.

Advice to doctor: The product contains low levels of DMSO which can act as a carrier across cell membranes. It contains animal proteins that could cause allergic reactions. Apart from the vaccine itself, any viable microorganisms present would have entered at the time of exposure.

Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: *Liquid nitrogen:* Cracked or improperly-sealed ampoules when placed in liquid nitrogen can cause leakage of liquid nitrogen into the ampoule. When removed from storage the rapid rise in pressure caused by the change from liquid to gaseous nitrogen can cause the ampoule to explode. Fire decomposition products from this product are likely to be irritating if inhaled.

Extinguishing Media: Not combustible. Use extinguishing media suited to burning materials. **Fire Fighting:** If a significant quantity of this product is involved in a fire, call the fire brigade.

Flash Point: Does not burn.

Upper Flammability Limit: Does not burn.

Lower Flammability Limit: Does not burn.

Autoignition Temperature: Not applicable - does not burn.

Flammability Class: Does not burn.

Section 6 - Accidental Release Measures

Accidental release: Treat the affected area with disinfectant (to inactivate the vaccine) while preventing run off from entering drains. In the unlikely event of a significant quantity of material entering drains, advise emergency services.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: Store packages of this product in liquid nitrogen. The storage area must be well ventilated so as to remove the gas generated to external air. Consult AS 1894 - 1976 Code of practice for the safe handling of Cryogenic Fluids. Provide adequate local exhaust and dilution ventilation. *Liquid nitrogen*: Cracked or improperly-sealed ampoules when placed in liquid nitrogen can cause leakage of liquid nitrogen into the ampoule. When removed from storage the rapid rise in pressure caused by the change from liquid to gaseous nitrogen can cause the ampoule to explode.

Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: **AS/NZS 4501** set 2008, Industrial Eye Protection: **AS 1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS 2210**.

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SWA Exposure Limits TWA (mg/m³) STEL (mg/m³)

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: This product should only be used in a well ventilated area. Consult AS 1894 - 1976 Code of practice for the safe handling of Cryogenic Fluids.

Eye Protection: Wear a polycarbonate face shield to protect against both splash and the shattering of ampoules. See AS 1336 and AS/NZS 1337.

Skin Protection: Wear overalls (see AS 2919) and boots capable of protecting against penetration of liquids (see AS/NZS 2210 - Occupational Protective Footwear). Wear gloves designed for use in freezers and use forceps to handle the product. Gloves **do not** allow the wearer to immerse any part of his or her hands in liquid nitrogen.

Protective Material Types: There is no specific recommendation for any particular protective material type. **Respirator:** Provided the operator is working in a well-ventilated area, a respirator is not necessary. Do **not** work with liquid nitrogen in small, poorly-ventilated areas without air drainage at floor level.

Safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

Other: Ear plugs or ear muffs should be worn when removing ampoules from liquid nitrogen, as an exploding ampoule may cause hearing loss and/or "ringing" in the ears. Always wash your hands after using the product.

Section 9 - Physical and Chemical Properties:

Physical Description & Colour: Frozen, pale pink or straw-coloured liquid in a labelled, sealed, clear glass

ampoule stored in liquid nitrogen.

Odour: No data.

Boiling Point: Not applicable.

Freezing/Melting Point: Decomposes before melting.

Volatiles:
Vapour Pressure:
No data.
Vapour Density:
Not applicable.
Specific Gravity:
No data.

Water Solubility:

pH:

Volatility:

No data.

No data.

No data.

No data.

Volatility:

No data.

Coeff Oil/Water Distribution: No data. **Viscosity:** Not applicable.

Autoignition Temperature: Not applicable - does not burn.

Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: This product should be kept in a cool place, preferably below 30°C. Containers should be kept dry. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: Acids, bases, oxidising agents.

Fire Decomposition: No specific data. Based on composition of proteins and fats, the following might be expected: Carbon dioxide, and if combustion is incomplete, carbon monoxide and possibly smoke. Nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Oxides of sulfur (sulfur dioxide is a respiratory hazard) and other sulfur compounds; also water.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Local Effects:

Target Organs: There is no data to hand indicating any particular target organs.

Classification of Hazardous Ingredients

Ingredient Risk Phrases

No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.

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Potential Health Effects

Inhalation:

Short Term Exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:

Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. In addition product is unlikely to cause any discomfort in normal use.

Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:

Short Term Exposure: This product may be mildly irritating to eyes, but is unlikely to cause anything more than mild discomfort which should disappear once product is removed.

Long Term Exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short Term Exposure: Significant oral exposure is considered to be unlikely. However, this product may be mildly irritating to mucous membranes but is unlikely to cause anything more than mild transient discomfort.

Long Term Exposure: No data for health effects associated with long term ingestion.

Injection:

Short Term Exposure: Needlestick injuries can occur when manual vaccination techniques are used. Resultant injuries are due to the effects of the penetration of the needle, its cleanliness at the time of penetration, the volume injected, and possibly some effect due to the presence of DMSO in the inoculum. The inoculum itself is not regarded as toxic, it is injected into day-old chicks or embryos as part of normal vaccination procedures.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA. **NTP:** No significant ingredient is classified as carcinogenic by NTP. **IARC:** No significant ingredient is classified as carcinogenic by IARC.

Section 12 - Ecological Information

Insufficient data to be sure of status. Expected to not be an environmental hazard.

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 14 - Transport Information

UN Number: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code Australian Code for the Transport of Dangerous Goods by Road and Rail (7th edition)

AICS

Australian Inventory of Chemical Substances

SWA

Safe Work Australia, formerly ASCC and NOHSC

CAS number

Chemical Abstracts Service Registry Number

Hazchem Code Emergency action code of numbers and letters that provide information to emergency

services especially firefighters

IARC International Agency for Research on Cancer

NOS Not otherwise specified

NTP National Toxicology Program (USA)

R-Phrase Risk Phrase

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SUSMP Standard for the Uniform Scheduling of Medicines & Poisons

UN Number United Nations Number

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS. OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)