

Section 1 - Identification of Chemical Product and Company

Issued by: Intervet Australia Pty Limited
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Chemical nature: Water suspension of inactivated *E. coli* in a suitable medium.
Trade Name: **ECOVac E. coli Vaccine for Pigs**
Product Code: 3631A (500mL) and 3631B (250mL)
Recommended Use: For protection against *E.coli* scours in neonatal pigs.
APVMA No: 35779
Creation Date: November, 2006
This version issued: October, 2021 and is valid for 5 years from this date.
Poisons Information Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification

Statement of Hazardous Nature:

This product is classified as: Hazardous according to the criteria of SWA.

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

SUSMP Classification: None allocated.

ADG Classification: None allocated. Not a Dangerous Good under the ADG Code.

UN Number: None allocated



GHS Signal word: **WARNING.**

Skin Sensitisation Category 1

HAZARD STATEMENT:

H317: May cause an allergic skin reaction.

PREVENTION

P102: Keep out of reach of children.

P261: Avoid breathing fumes, mists, vapours or spray.

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

P272: Contaminated work clothing should not be allowed out of the workplace.

P281: Use personal protective equipment as required.

RESPONSE

P337: If eye irritation persists: seek medical attention.

P363: Wash contaminated clothing before reuse.

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

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P333+P313: If skin irritation or rash occurs: Get medical advice.

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

STORAGE

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P402+P404: Store in a dry place. Store in a closed container.

P403+P235: Store in a well-ventilated place. Keep cool.

DISPOSAL

P501: Dispose of contents and containers as specified on the registered label.

Emergency Overview

Physical Description & Colour: Slightly opaque beige liquid.

Odour: No odour.

Major Health Hazards: possible skin sensitiser.

Section 3 - Composition/Information on Ingredients

| Ingredients | CAS No | Conc,% | TWA (mg/m ³) | STEL (mg/m ³) |
|----------------------------------------------------------------------------------------|-----------|--------|--------------------------|---------------------------|
| K88, K99 and 987P Fimbriated and Non Fimbriated inactivated strains of <i>E.coli</i> . | | | not set | not set |
| Formaldehyde | 50-00-0 | 0.2 | 1.2 | 2.5 |
| Thiomersal | 554-64-8 | 0.1 | not set | not set |
| Aluminium Hydroxide (adjuvant) | | | not set | not set |
| Isotonic saline | 7732-18-5 | to 100 | not set | not set |

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

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.

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.

Self Injection: Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed vaccine. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied.

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

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

Eye Contact: 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.

Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a

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fire. This will only occur after heating to dryness.

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: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling vaccines. In the event of a major spill, prevent spillage from entering drains or water courses and call 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: Refrigerate, preferably between 2 and 8°C, but do not freeze. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Some liquid preparations settle or separate on standing and may require stirring before use. Check packaging - there may be further storage instructions on the label.

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: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

| SWA Exposure Limits | TWA (mg/m ³) | STEL (mg/m ³) |
|---------------------|--------------------------|---------------------------|
| Formaldehyde | 1.2 | 2.5 |

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 where there is ventilation that is adequate to keep exposure below the TWA levels. If necessary, use a fan.

Eye Protection: Eye protection is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

Skin Protection: If you believe you may have a sensitisation to this product or any of its declared ingredients, you should prevent skin contact by wearing impervious gloves, clothes and, preferably, apron. Make sure that all skin areas are covered. See below for suitable material types.

Protective Material Types: We suggest that protective clothing be made from the following materials: rubber, PVC.

Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Section 9 - Physical and Chemical Properties

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|-------------------------------------------|--------------------------------------------|
| Physical Description & Colour: | Slightly opaque beige liquid. |
| Odour: | No odour. |
| Boiling Point: | Approximately 100°C at 100kPa. |
| Freezing/Melting Point: | Approximately 0°C. |
| Volatiles: | Water component. |
| Vapour Pressure: | 2.37 kPa at 20°C (water vapour pressure). |
| Vapour Density: | No data. |
| Specific Gravity: | No data. |
| Water Solubility: | Completely soluble in water. |
| pH: | 6.0 to 8.0 |
| Volatility: | Negligible at normal ambient temperatures. |
| Odour Threshold: | No data. |
| Evaporation Rate: | No data. |
| Coeff Oil/water Distribution: | No data |
| Autoignition temp: | 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: 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 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. Water. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Local Effects:

Target Organs: skin

Classification of Hazardous Ingredients

| Ingredient | Risk Phrases |
|--------------|------------------------|
| Formaldehyde | >=0.2%Conc<1%: Xi; R43 |

Potential Health Effects

Inhalation:

Short Term Exposure: Available data indicates that this product is not harmful. However product may be mildly irritating, although unlikely to cause anything more than mild transient discomfort.

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

Skin Contact:

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Short Term Exposure: Classified as a potential sensitiser by skin contact. Exposure to a skin sensitiser, once sensitisation has occurred, may manifest itself as skin rash or inflammation, and in some individuals this reaction can be severe. However 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. This product is unlikely to cause any irritation problems in the short or long term.

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

Carcinogen Status:

SWA: Formaldehyde is classified by SWA as a Class 3 Carcinogen, possibly carcinogenic to humans.

See the SWA website for further details. A web address has not been provided as addresses frequently change.

NTP: Formaldehyde is classified by NTP as reasonably anticipated to be carcinogenic to humans.

See the NTP website for further details. A web address has not been provided as addresses frequently change.

IARC: Formaldehyde is classed 1 by IARC - carcinogenic to humans.

See the IARC website for further details. A web address has not been provided as addresses frequently change.

Section 12 - Ecological Information

This product is biodegradable. It will not accumulate in the soil or water or cause long term problems.

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. 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.

The following ingredient: Formaldehyde, is mentioned in the SUSMP.

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 |

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|------------------|------------------------------------------------------------|
| NOS | Not otherwise specified |
| NTP | National Toxicology Program (USA) |
| R-Phrase | Risk Phrase |
| 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" (Feb 2016)

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