

## Section 1 - Identification of the Substance/Mixture and Supplier

### Zoetis Australia Pty Ltd

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<b>Product Identifier:</b>	<b>Ultravac<sup>®</sup> Scourshield<sup>®</sup> Vaccine</b>
<b>Other names:</b>	None
<b>Chemical family:</b>	Not applicable.
<b>APVMA Approval No:</b>	65032/49934
<b>Recommended Use:</b>	For the vaccination of healthy, pregnant cows and heifers as an aid in preventing diarrhoea in their calves caused by bovine rotavirus (serotypes G6 and G10) and enterotoxigenic strains of E. coli having the K99 pili adherence factor, and for control of diarrhoea in their calves caused by bovine coronavirus.
<b>Restrictions on use</b>	For veterinary use only.
<b>Emergency Phone:</b>	<b>1800 814 883 (all hours)</b>

## 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 the Australian Dangerous Goods (ADG) Code.

**Risk Phrases:** Not Hazardous - No criteria found.

**Safety Phrases:** S24/25. Avoid contact with skin and eyes.

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

### GHS Classification:

### GHS Label Elements: None

### Signal word: NONE. Not hazardous.

#### HAZARD STATEMENT:

None.

#### PRECAUTIONARY STATEMENTS

None.

#### PREVENTION

P102: Keep out of reach of children.

P280: Wear protective gloves, protective clothing and eye or face protection.

#### RESPONSE

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

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

#### STORAGE

P411: Store at temperatures not exceeding 8°C.

#### 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.

**Other / supplementary hazards:** None

## Emergency Overview

**Physical Description & colour:** Liquid solution in multiple-dose vials.

**Odour:** No data re odour.

Acute toxicity following ingestion is not expected. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. Saponins have little toxicity for humans when ingested but have haemolytic effects when injected intravenously.

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Issued by: Zoetis Australia Pty Ltd

Phone: 1800 814 883

Poisons Information Centre: 13 1126 from anywhere in Australia

## Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m <sup>3</sup> )	STEL (mg/m <sup>3</sup> )
Adjuvant	secret	secret	not set	not set
Gentamicin	1403-66-3	trace	not set	not set
Formaldehyde	50-00-0	< 0.1	1.2	2.5
Merthiolate (as mercury)	54-64-8	trace	not set	not set
Bovine coronavirus	not set		not set	not set
Bovine rotavirus	not set		not set	not set
<i>Escherichia coli</i>	not set		not set	not set
Water	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 1126 from anywhere in Australia 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. Check your tetanus immunisation status.

**Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** No data available

**Medical Conditions Aggravated by Exposure:** None known

### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

## Section 5 - Fire Fighting Measures

**Hazards arising from the product:** The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. 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 product at temperatures normally achieved in a fire. This will only occur after heating to dryness.

Fire decomposition products from this product are not expected to be hazardous or harmful. Only small amounts or decomposition products may be released by this product. Based on composition of proteins, the following might be expected: Carbon dioxide, and if combustion is incomplete, carbon monoxide. 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.

**Suitable Extinguishing Media:** Not combustible. Use extinguishing media suited to burning materials.

**Special Protective Equipment and Precautions for Firefighters:** If a significant quantity of this product is involved in a fire, call the fire brigade.

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Hazchem Code: None allocated.

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## Section 6 - Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures:

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 injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

### Environmental Precautions

For empty containers follow label instructions for disposal. Where containers are not empty, place waste in an appropriately labelled, sealed container for disposal. Seek advice about appropriate disposal considerations from your local authority. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labelled container for disposal.

**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.

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## 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. Protect from light. 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.

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## Section 8 - Exposure Controls and Personal Protection

### Control Parameters:

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 <sup>3</sup> )	STEL (mg/m <sup>3</sup> )
Formaldehyde	1.2	2.5

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.

### Gentamicin

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

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.

**Engineering Controls:** No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that vapours and mists are minimised.

**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:** The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products and that you wear suitable gloves (preferably elbow-length) when skin contact is likely.

**Protective Material Types:** There is no data that enables us to recommend any type except that it should be impermeable.

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

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## Section 9 - Physical and Chemical Properties:

<b>Appearance:</b>	Liquid solution in multiple-dose vials.
<b>Odour:</b>	No data re odour.
<b>Odour Threshold:</b>	No data.
<b>pH:</b>	No data.
<b>Freezing/Melting Point:</b>	Approximately 0°C.
<b>Boiling Point:</b>	Above 100°C at 100kPa.
<b>Flash point:</b>	Does not burn.
<b>Upper Flammability Limit:</b>	Does not burn.
<b>Lower Flammability Limit:</b>	Does not burn.
<b>Autoignition temperature:</b>	Not applicable - does not burn.
<b>Flammability (solid, gas):</b>	Not applicable.
<b>Flammability Class:</b>	Does not burn.
<b>Decomposition Temperature:</b>	No data.
<b>Volatiles:</b>	Water component.
<b>Vapour Pressure:</b>	2.37 kPa at 20°C (water vapour pressure).
<b>Vapour Density:</b>	As for water.
<b>Relative Density:</b>	0.8-1.2.
<b>Water Solubility:</b>	Completely soluble in water.
<b>Solvent Solubility:</b>	No data.
<b>Volatility:</b>	No data.
<b>Evaporation Rate:</b>	As for water.
<b>Partition Coefficient (n-octanol/water):</b>	No data.
<b>Viscosity:</b>	No data.

## 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.

### Stability:

**Conditions to Avoid:** 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.

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

**Hazardous Decomposition Products:** Only small amounts or decomposition products may be released by this product. Based on composition of proteins, the following might be expected: Carbon dioxide, and if combustion is incomplete, carbon monoxide. 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. 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

### Symptoms caused by Exposure

**General Information:** The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The primary hazards are due to the formaldehyde content. Persons sensitised to formaldehyde should avoid contact with this product.

**Routes of exposure:** Inhalation, skin contact, eye contact

### Symptoms of exposure:

#### Inhalation:

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

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**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 is believed to be not irritating to eyes.

**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.

**This toxicology of this formulation has not been determined. The information included in this section describes the potential hazards of the individual ingredients..**

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

**Adjuvant**

Rat IV LD<sub>50</sub> 670 µg/kg

**Merthiolate (as mercury)**

Rat Oral LD<sub>50</sub> 75 mg/kg

Rat Subcutaneous LD<sub>50</sub> 98 mg/kg

**Gentamicin**

Rat Oral LD<sub>50</sub> 6600 mg/kg

Rat Subcutaneous LD<sub>50</sub> 710 mg/kg

Mouse IM LD<sub>50</sub> 167 mg/kg

Rat IM LD<sub>50</sub> 463 mg/kg

**Formaldehyde**

Rat Oral LD<sub>50</sub> 800 mg/kg

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

**Merthiolate (as mercury)**

Eye Irritation Rabbit Mild

**Gentamicin**

Eye Irritation Rabbit Non-irritating

**Formaldehyde**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

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

**Formaldehyde**

90 Day(s) Rat Inhalation Not Specified Lungs

90 Day(s) Dog Inhalation Not Specified Lungs

90 Day(s) Monkey Inhalation Not Specified Lungs

9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

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

**Gentamicin**

Embryo / Foetal Development Rat Intramuscular 75 mg/kg/day LOAEL Developmental toxicity

**Formaldehyde**

Embryo / Foetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity

Embryo / Foetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

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

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive

*In Vitro* Chromosome Aberration Rodent Positive

*In Vitro* Sister Chromatid Exchange Rodent Positive

*In Vivo* Chromosome Aberration Not specified Positive

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

**Formaldehyde**

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumours

2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumours

## Classification of Hazardous Ingredients

**Ingredient**

**Risk Phrases**

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

**Gentamicin:** LD<sub>50</sub> Oral, Rat 6600mg/kg

**Formaldehyde:** LD<sub>50</sub> Oral, Rat 800mg/kg

**Respiratory or Skin Sensitisation:** Formaldehyde is classed by SWA as a potential sensitiser by skin contact.

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**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.

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**Section 12 - Ecological Information**

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

**Toxicity information:** No data

**Persistence and degradability:** No data

**Bioaccumulation potential:** No data

**Mobility in Soil:** No data

**Other adverse effects:** No data

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**Section 13 - Disposal Considerations**

**Disposal:** For empty containers follow label instructions for disposal. Where containers are not empty, place waste in an appropriately labeled, sealed container for disposal. Seek advice about appropriate disposal considerations from your local authority. Care should be taken to avoid environmental release.

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**Section 14 - Transport Information**

**UN Number:** This product is not classified as a Dangerous Good. No special transport conditions are necessary unless required by other regulations.

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**Section 15 - Regulatory Information**

**Poison Schedule:** None allocated.

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

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**Section 16 - Other Information**

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

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

**Acronyms:**

<b>ADG Code</b>	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 <sup>th</sup> edition)
<b>AICS</b>	Australian Inventory of Chemical Substances
<b>SWA</b>	Safe Work Australia, formerly ASCC and NOHSC
<b>CAS number</b>	Chemical Abstracts Service Registry Number
<b>Hazchem Code</b>	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
<b>IARC</b>	International Agency for Research on Cancer
<b>NOS</b>	Not otherwise specified
<b>NTP</b>	National Toxicology Program (USA)
<b>R-Phrase</b>	Risk Phrase
<b>SUSMP</b>	Standard for the Uniform Scheduling of Medicines & Poisons
<b>UN Number</b>	United Nations Number

**This version issued: November, 2015** and is valid until March, 2019.

**Supersedes:** version issued 20 January 2014

**SAFETY DATA SHEET**

**Revision History:**

Date of Revision	Reason
20/01/2014	First issue
14/03/2014	Correct storage conditions
20/11/2015	Update Zoetis Address

**Contact Points:**

<b>Zoetis</b>	<b>1800 814 883</b>
<b>Police and Fire Brigade:</b>	<b>Dial 000</b>

**If ineffective:****Dial Poisons Information Centre  
(13 1126 from anywhere in Australia)**

THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.

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)

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**End of Safety Data Sheet**

**SAFETY DATA SHEET**