

SAFETY DATA SHEET



1. Identification

Product identifier	Ultravac® Scourshield® Vaccine
Other means of identification	
Synonyms	BOVINE ROTAVIRUS G6, BOVINE ROTAVIRUS G10, BOVINE CORONAVIRUS, E. Coli K99
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary vaccine
Restrictions on use	Not for human use
Details of manufacturer or importer	
Company Name (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	productsupport.au@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.

Label elements, including precautionary statements

Hazard symbol(s)	None.
Signal word	None.
Hazard statement(s)	The mixture does not meet the criteria for classification.
Precautionary statement(s)	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Other hazards which do not result in classification None known.

Supplemental information In the event of accidental injection, an allergic reaction may occur. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Bovine rotavirus	Not assigned	
Bovine coronavirus	Not assigned	
Escherichia coli	Not assigned	
Formaldehyde	50-00-0	<0.1

Merthiolate (as mercury)	54-64-8	##
Gentamicin	1403-66-3	##
Adjuvant	8047-15-2	
Diluent	7732-18-5	

Composition comments % = w/v
 ## Trace

4. First-aid measures

Description of necessary first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.

Ingestion Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Personal protection for first-aid responders 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 (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

Medical attention and special treatment Treat symptomatically. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Hazchem code None.

General fire hazards No unusual fire or explosion hazards noted.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapour. Do not get in eyes, on skin, or on clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Avoid release to the environment. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. Put material in suitable, covered, labeled containers. For waste disposal, see section 13 of the SDS.

7. Handling and storage**Precautions for safe handling**

Wear personal protective equipment. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid breathing mist or vapour. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store away from incompatible materials (see Section 10 of the SDS). Store away from direct sunlight. Protect from heat and light. @ 2 - 8°C (36 - 46°F). Do not freeze. Keep container tightly closed. Keep away from heat, sparks and open flame.

8. Exposure controls and personal protection**Control parameters**

Follow standard monitoring procedures.

Occupational exposure limits**Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)**

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m ³
		2 ppm
	TWA	1.2 mg/m ³
Merthiolate (as mercury) (CAS 54-64-8)		1 ppm
	STEL	0.03 mg/m ³
	TWA	0.01 mg/m ³

US. ACGIH Threshold Limit Values

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	0.3 ppm
		0.1 ppm
	TWA	0.1 ppm
Merthiolate (as mercury) (CAS 54-64-8)	STEL	0.03 mg/m ³
		0.01 mg/m ³
	TWA	0.01 mg/m ³

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m ³
		2 ppm
	TWA	2.5 mg/m ³
		2 ppm

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	TWA	0.37 mg/m ³
		0.3 ppm

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

US ACGIH Threshold Limit Values: Skin designation

Merthiolate (as mercury) (CAS 54-64-8)

Can be absorbed through the skin.

Control banding approach

Gentamicin: Zoetis OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Appropriate engineering controls

General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Wear appropriate chemical resistant gloves.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards

Not applicable.

Hygiene measures

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state

Liquid.

Form

Liquid.

Colour

Not available.

Odour

Not available.

Odour threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapour pressure

Not available.

Vapour density

Not available.

Relative density

Not available.

Solubility(ies)

Solubility (water)

Soluble

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other physical and chemical parameters

Explosive properties

Not explosive.

Oxidising properties Not oxidising.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Sunlight. Avoid high temperatures. Protect from freezing. Keep away from heat, sparks and open flame.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on possible routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Prolonged skin contact may cause temporary irritation.
Formaldehyde Species: Rabbit
Severity: Moderate Severe

Eye contact Direct contact with eyes may cause temporary irritation.
Merthiolate (as mercury) Species: Rabbit
Severity: Mild

Gentamicin Species: Rabbit
Severity: Non-irritating

Formaldehyde Species: Rabbit
Severity: Severe

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to exposure Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients.

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
Adjuvant (CAS 8047-15-2)		
Acute		
Inhalation		
LC50	Rat	0.824 mg/l
Oral		
LD50	Rat	1144 mg/kg
Formaldehyde (CAS 50-00-0)		
Acute		
Inhalation		
LC50	Rat	0.48 mg/l, 4 Hours
Oral		
LD50	Rat	800 mg/kg 100 mg/kg

Components	Species	Test Results
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumours
	Rat	15 ppm, 9 days Respiratory system
		6 ppm, 2 years Tumours
Gentamicin (CAS 1403-66-3)		
Acute		
Intramuscular		
LD50	Mouse	167 mg/kg
	Rat	463 mg/kg
Oral		
LD50	Rat	6600 mg/kg
Subcutaneous		
LD50	Rat	710 mg/kg
Merthiolate (as mercury) (CAS 54-64-8)		
Acute		
Oral		
LD50	Rat	75 mg/kg
Subcutaneous		
LD50	Rat	98 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/irritation	Direct contact with eyes may cause temporary irritation.	
Eye contact		
Merthiolate (as mercury)	Species: Rabbit	Severity: Mild
Gentamicin	Species: Rabbit	Severity: Non-irritating
Formaldehyde	Species: Rabbit	Severity: Severe
Respiratory or skin sensitisation		
ACGIH sensitisation		
FORMALDEHYDE (CAS 50-00-0)	Dermal sensitization Respiratory sensitisation	
Respiratory sensitisation	Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.	
Skin sensitisation	Based on available data, the classification criteria are not met. This product contains formaldehyde and merthiolate which are considered to be skin sensitizers. In the event of accidental injection, an allergic reaction may occur.	
Germ cell mutagenicity		
Mutagenicity		
Formaldehyde	In Vitro Bacterial Mutagenicity (Ames) Result: positive Species: Bacteria	
	In Vitro Chromosome Aberration Result: positive Species: Rodent	
	In Vitro Sister Chromatid Exchange Result: positive Species: Rodent	

Mutagenicity
Formaldehyde

In Vivo Chromosome Aberration
Result: positive
Species: Not specified

Carcinogenicity

Based on available data, the classification criteria are not met. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

ACGIH Carcinogens

Formaldehyde (CAS 50-00-0)

A1 Confirmed human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0)

1 Carcinogenic to humans.

Reproductive toxicity

Based on available data, the classification criteria are not met.

Developmental effects

Formaldehyde

185 mg/kg/day Embryo / Fetal Development, Not teratogenic
Maternal toxicity
Species: Mouse
Organ: Oral

40 ppm Embryo / Fetal Development, Not Teratogenic
Maternal Toxicity
Species: Rat
Organ: Inhalation

Gentamicin

75 mg/kg/day Embryo / Fetal Development, Developmental toxicity
Result: LOAEL
Species: Rat
Organ: Intramuscular

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Not classified.

Aspiration hazard

Based on available data, the classification criteria are not met.

Other information

The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

12. Ecological information

Ecotoxicity

Based on available data, the classification criteria are not met for hazardous to the aquatic environment. The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components

Species

Test Results

Formaldehyde (CAS 50-00-0)

Aquatic

Crustacea

EC50

Water flea (*Daphnia pulex*)

4.3 - 7.8 mg/l, 48 hours

Fish

LC50

Striped bass (*Morone saxatilis*)

10.302 - 16.743 mg/l, 96 hours

Persistence and degradability

No data available for this product.

Bioaccumulative potential

No data available for this product.

Mobility in soil

No data available for this product.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal methods	Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.
Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

ADG	Not regulated as dangerous goods.
RID	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

Safety, health and environmental regulations

National regulations	This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals. APVMA No. 65032 Poison Schedule (Product) – Schedule 0 This SDS replaces version: issued November 2015
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Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Formaldehyde (CAS 50-00-0)
Merthiolate (as mercury) (CAS 54-64-8)

Australia Medicines & Poisons Appendix F

Formaldehyde (CAS 50-00-0)

Australia Medicines & Poisons Appendix G

Merthiolate (as mercury) (CAS 54-64-8)

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Formaldehyde (CAS 50-00-0)

Australia Medicines & Poisons Schedule 2

Formaldehyde (CAS 50-00-0)

Merthiolate (as mercury) (CAS 54-64-8)

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Gentamicin (CAS 1403-66-3)

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Formaldehyde (CAS 50-00-0)

Australia Medicines & Poisons Schedule 7

Merthiolate (as mercury) (CAS 54-64-8)

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

Australia National Pollutant Inventory (NPI): Threshold quantity

Formaldehyde (CAS 50-00-0)

10 TONNES/YR Threshold Category: 1

Merthiolate (as mercury) (CAS 54-64-8)

5 kg Threshold Category: 1B

High Volume Industrial Chemicals (HVIC)

Diluent (CAS 7732-18-5)

1000 - 9999 TONNES See the regulation for additional information.

Formaldehyde (CAS 50-00-0)

10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Merthiolate (as mercury) (CAS 54-64-8)

2000 TONNES/YR Threshold Category: 2B

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Merthiolate (as mercury) (CAS 54-64-8)

Pesticide

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date

13-January-2021

Disclaimer

Zoetis Inc. believes that the information contained in this 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. The information in the sheet was written based on the best knowledge and experience currently available.