SAFETY DATA SHEET

1. Identification

Product identifier: DUVAXYN R

Other means of identification:

Synonyms: Duvaxyn® R Equine Rotavirus Vaccine (Inactivated) * EQUIP Rotavirus * Equine Rota

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. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

3. Composition/information on ingredients

Mixture:

Identity of chemical ingredients | CAS number and other unique identifiers | Concentration of ingredients (%)
--- | --- | ---
Inactivated Equine Rotavirus H2 strain | Not assigned | 
Neomycin | 1404-04-2 | ##
Squalene | 111-02-4 | 

Material name: DUVAXYN R

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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. Self Injection: In all instances of accidental self injection contact a doctor as soon as possible. Further information on treatment is available from Poisons Information Centre - Phone 131 126. 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. Check your tetanus immunisation status.

**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**
IF exposed or concerned: Get medical advice/attention. 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. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. For personal protection, see section 8 of the SDS.

5. Fire-fighting measures

**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. Material will burn in a fire.

**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. Material will burn in a fire.

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.

For emergency responders
Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up
Ensure adequate ventilation. Avoid inhalation of vapours or mists. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. 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. 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 breathing mist or vapour. Avoid accidental injection. 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 out of direct sunlight in dark, dry conditions. @ 2 - 8°C (36 - 46°F). Do not freeze. Protect from light. Store in original tightly closed container. Keep away from heat, sparks and open flame. Store away from incompatible materials (see Section 10 of the SDS). Store as directed by product packaging.

8. Exposure controls and personal protection

Control parameters
Follow standard monitoring procedures.

Occupational exposure limits

<table>
<thead>
<tr>
<th>Zoetis Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neomycin (CAS 1404-04-2)</td>
<td>TWA</td>
<td>100 µg/m³</td>
</tr>
</tbody>
</table>

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thimerosal (CAS 54-64-8)</td>
<td>STEL</td>
<td>0.03 mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>0.01 mg/m³</td>
</tr>
</tbody>
</table>

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
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US. ACGIH Threshold Limit Values

<table>
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<tr>
<th>Components</th>
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Biological limit values
No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Australia OELs: Skin designation
Thimerosal (CAS 54-64-8) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation
Thimerosal (CAS 54-64-8) Can be absorbed through the skin.
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 protective gloves.

Other

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

Respiratory protection

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

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

Emulsion.

Physical state

Liquid.

Form

Liquid.

Colour

Not available.

Odour

Not available.

Odour threshold

Not available.

pH

Not available.

Melting point/freezing point

< 0 °C (< 32 °F) estimated

Initial boiling point and boiling range

100 °C (212 °F) @ 100 kPa estimated

Flash point

Non-flammable

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) Not available.

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.
Material is stable under normal conditions.

No dangerous reaction known under conditions of normal use.

Contact with incompatible materials. Sunlight. Avoid high temperatures. Do not allow material to freeze. Keep away from heat, sparks and open flame.

Strong oxidising agents.

No hazardous decomposition products are known.

11. Toxicological information

Information on possible routes of exposure

Inhalation: No adverse effects due to inhalation are expected.

Skin contact: No adverse effects due to skin contact are expected.

Eye contact: Direct contact with eyes may cause temporary irritation.

Species: Rabbit

Severity: Mild

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. 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.

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

Components | Species | Test Results
--- | --- | ---
Neomycin (CAS 1404-04-2) | Acute | Oral LD50 Rat 2750 mg/kg
Thimerosal (CAS 54-64-8) | Acute | Oral LD50 Mouse 91 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.

Species: Rabbit

Severity: Mild

Respiratory or skin 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. In the event of accidental injection, an allergic reaction may occur.

Germ cell mutagenicity: No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity: Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity: This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity -
single exposure  Not classified.
Specific target organ toxicity -
repeated exposure  Not classified.
Aspiration hazard  Due to partial or complete lack of data the classification is not possible.
Other information  The antigens included in this product are non-infectious. All have been prepared from
killed or inactivated preparations of microorganisms.

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.
Persistence and degradability  No data available for this product.
Bioaccumulative potential  No data available for this product. Not expected to bioaccumulate.
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 dispose of waste into sewer. 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 the Australia Model Code of Practice for
the preparation of safety data sheets for hazardous chemicals.
Poison Schedule (Product) – Schedule 0
APVMA no. 56501
This SDS replaces version issued 6 June 2014.

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
Thimerosal (CAS 54-64-8)

Australia Medicines & Poisons Appendix F
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G
Thimerosal (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
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2
Thimerosal (CAS 54-64-8)

Australia Medicines & Poisons Schedule 3
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4
Neomycin (CAS 1404-04-2)

Australia Medicines & Poisons Schedule 5
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7
Thimerosal (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
Thimerosal (CAS 54-64-8) 5 kg Threshold Category: 1B

High Volume Industrial Chemicals (HVIC)
Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)
Not listed.

National Pollutant Inventory (NPI) substance reporting list
Thimerosal (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
   Thimerosal (CAS 54-64-8)   Pesticide

Kyoto Protocol
   Not applicable.

Montreal Protocol
   Not applicable.

Basel Convention
   Not applicable.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

* 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
   01-July-2019

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.

Revision information
   Product and Company Identification: Synonyms
   Composition / Information on Ingredients: Ingredients
   Physical & Chemical Properties: Multiple Properties
   GHS: Classification