SAFETY DATA SHEET



1. Identification

Product identifier Equity® Oestrus Control Vaccine for Horses

Other means of identification

Synonyms Oestrus control for horses

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product used as synthetic hormonal agent

Restrictions on use Not for human use

Details of manufacturer or importer

Manufacturer

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 australia.animalhealth@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 Reproductive toxicity Category 1B

Environmental hazards Not classified.

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard

Signal word Danger

Hazard Statement(s) May damage fertility or the unborn child.

Precautionary Statement(s)

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Use personal protective equipment as required.

Response IF exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards which do not

result in classification

None known.

Supplemental information

In the event of systemic exposure, this material may cause immune system reactions in humans. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy. Pregnant women should not administer this product. Women and men of childbearing age should exercise extreme caution when handling this product. In the event of accidental injection, an allergic reaction may occur. Accidental self injection could affect reproductive physiology of both men and women and may adversely affect pregnancy. After self injection or needle stick injury do not administer the product, and/or any other product with similar action, in the future.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate	Not assigned	0.02
Thimerosal	54-64-8	0.01
Synthetic Adjuvant	Not assigned	*
Water for injection	7732-18-5	*

Composition comments

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Description of necessary first aid measures

Inhalation

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

If inhaled, remove to fresh air. Get medical attention immediately.

In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event Skin contact

of accidental self injection or needle stick injury, wash the injury thoroughly with clean running

water. Get medical attention immediately.

Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Eye contact

Continue rinsing. Get medical attention immediately.

IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. Rinse mouth Ingestion

thoroughly. Never give anything by mouth to an unconscious person.

Personal protection for first-aid

responders

IF exposed or concerned: Get medical advice/attention. 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. Accidental self injection could affect reproductive physiology of both men and women and may adversely affect pregnancy. After self injection or needle stick injury do not administer the product, and/or any other product with similar action, in the future.

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. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and maintenance of pregnancy.

Medical attention and special

treatment

Accidental self injection could affect reproductive physiology of both men and women and may adversely affect pregnancy. After self injection or needle stick injury do not administer the product, and/or any other product with similar action, in the future.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

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

Fire fighting

equipment/instructions

Move containers from fire area if you can do so without risk.

Hazchem Code

General fire hazards

No unusual fire or explosion hazards noted.

Material name: Equity® Oestrus Control Vaccine for Horses

None.

SDS AUSTRALIA

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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders

Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Avoid contact with eyes, skin, and 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. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. 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

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Pregnant women should not administer this product. Women and men of childbearing age should exercise extreme caution when handling this product. Special care should be taken to avoid accidental self injection and needle stick injury when administering the product. Use a safety injector, preferably one which has a dual safety system providing both a needle guard and a mechanism to prevent accidental operation of the trigger. Handle and open container with care. Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wash thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Protect from light. Refrigeration recommended. 2 - 8°C (36 - 46°F). Do not freeze. Store away from incompatible materials (see Section 10 of the SDS). Use care in handling/storage.

8. Exposure controls and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

Australia. National Workplace OE Components	Ls (Workplace Exposure Star Type	ndards for Airborne Contaminants, Appendix A) Value
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3
Australia. OELs. (Adopted Nation Environment)	al Exposure Standards for At	mospheric Contaminants in the Occupational
Components	Туре	Value
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3
US. ACGIH Threshold Limit Value	es	
Components	Туре	Value
Thimerosal (CAS 54-64-8)	STEL	0.03 mg/m3
	TWA	0.01 mg/m3

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.

Gonadotropin Releasing Factor Analog - Diphtheria Toxoid Conjugate: Zoetis OEB 4 (control Control banding approach

exposure to the range of 1ug/m3 to <10ug/m3)

Appropriate engineering

controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

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

If contact is likely, safety glasses with side shields are recommended. Eye/face protection

Skin protection

Hand protection Wear impervious gloves if skin contact is possible.

Other Impervious protective clothing is recommended if skin contact with drug product is possible and for

bulk processing operations.

Respiratory protection No personal respiratory protective equipment normally required. If engineering controls do not

maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Chemical respirator with organic vapour cartridge and

full facepiece.

not applicable. Thermal hazards

Observe any medical surveillance requirements. Always observe good personal hygiene Hygiene measures

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 Clear, colorless Not available. Odour **Odour threshold** Not available.

6.7

Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

Not available. Flash point **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 (%) Explosive limit – upper

Not available. Not available.

(%)

Vapour pressure Not available. Vapour density Not available. Relative density Not available.

Solubility(ies)

100 % Solubility (water)

Not available. Partition coefficient

(n-octanol/water)

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature** Not available. **Viscosity**

Other physical and chemical parameters

Explosive properties Not explosive. Not oxidising. Oxidising properties

Specific gravity 1.05

10. Stability and reactivity

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

Chemical stability Material is stable under normal conditions.

Possibility of hazardous No dangerous reaction known under conditions of normal use. Hazardous polymerisation does not

reactions

Conditions to avoid Contact with incompatible materials. Exposure to light. Avoid high temperatures.

Incompatible materials Strong oxidising agents.

No hazardous decomposition products are known. Thermal decomposition products may include Hazardous decomposition products

oxides of carbon, nitrogen, and sulfur.

11. Toxicological information

Information on possible routes of exposure

Inhalation No adverse effects due to inhalation are expected. No adverse effects due to skin contact are expected. Skin contact Direct contact with eyes may cause temporary irritation. Eye contact

Thimerosal Species: Rabbit

Severity: Mild

Ingestion Expected to be a low ingestion hazard.

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, Symptoms related to exposure

> redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Systemic exposure may affect reproductive hormone regulation and thus affect fertility and

maintenance of pregnancy.

Components **Species Test results**

Thimerosal (CAS 54-64-8)

Acute Oral

> LD50 Mouse 91 mg/kg 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.

Eve contact

Thimerosal Species: Rabbit Severity: Mild

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitizer.

This product is not expected to cause skin sensitisation. Skin sensitisation

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 May damage fertility or the unborn child. Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard

Not an aspiration hazard.

Other information

The toxicity of similar GnRF biologicals has been evaluated in several species. In all species tested, vaccination was associated with significant changes in sex hormone balance with severe

consequences to reproduction and development.

12. Ecological information

Ecotoxicity

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 is available on the degradability of this product.

Bioaccumulative potential

no data available.

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 discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Incinerate the material under controlled conditions in an approved incinerator. If no on-site incinerator is available, dispose of material in a licensed commercial chemical incinerator. Dispose of contents/container in accordance with local/regional/national/international regulations. Contract

with a disposal operator licensed by the Law on Disposal and Cleaning.

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. Do not re-use empty containers.

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

Not available.

the IBC Code

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 (23/12/2011).

APVMA No: 53542

Poison Schedule (Product) - Schedule 4

This SDS replaces version issued: 18 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 C

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)

For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If skin or hair contact occurs, remove contaminated

clothing and flush skin and hair with running water.

Exception may apply, see the regulation for relevance.

in preparations for human external use For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New

Zealand 03 - 4747 - 000) or a doctor (at once).

Mercury

for external use

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 2

Thimerosal (CAS 54-64-8)

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

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)

Water for injection (CAS 7732-18-5) 1000 - 9999 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

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.

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

Not listed.

Restricted Carcinogenic Substances

Not regulated.

Material name: Equity® Oestrus Control Vaccine for Horses

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Thimerosal (CAS 54-64-8) Pesticide

Inventory name

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

Country(s) or region

International Inventories

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
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

^{*}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).

Toxic Substances Control Act (TSCA) Inventory

16. Other information

United States & Puerto Rico

Issue date 31-August-2016

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

Regulatory Information: United States

On inventory (yes/no)*

No