

Section 1 - Identification of the Substance/Mixture and Supplier

Zoetis Australia Pty Ltd

ABN 94 156 476 425

Level 6, 5 Rider Blvd

Rhodes NSW 2138 AUSTRALIA

Tel: 1800 814 883

Fax: (02) 8876 0444

Email: australia.animalhealth@zoetis.com



Product Identifier:	EAZI-BREED CIDR® Sheep and Goat Device
APVMA Code:	49895
Other names:	None
Chemical family:	Delivers progesterone which is a female sex hormone
Recommended Use:	Intravaginal hormonal device for oestrus synchronisation (controlled breeding) in sheep and goats.
Restrictions on use	For veterinary use only
Emergency Phone:	1800 814 883 (all hours)

Section 2 - Hazards Identification

Appearance: Solid

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

Carcinogenicity: Category 1B

Label Elements

Signal Word:

Danger

Hazard Statements:

H350 - May cause cancer

H360 - May damage fertility or the unborn child

Precautionary Statements:

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects:

Based on human experience, possible adverse effects following exposure to this compound may include menstrual irregularities weight changes fluid retention drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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Issued by: Zoetis Australia Pty Ltd

Phone: 1800 814 883

Poisons Information Centre: 13 11 26 from anywhere in Australia

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3 - Composition/Information on Ingredients

Hazardous

Ingredients	CAS No	Conc,%	GHS Classification
Progesterone	57-83-0	0.30 gm/insert	Carc. 1B (H350) Repr. 1B (H360FD)

Ingredients	CAS No	Conc,%	GHS Classification
Silicone rubber	63394-02-5	*	Not Listed
Nylon 66	32131-17-2	*	Not Listed

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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

Section 4 - First Aid Measures

Description of First Aid Measures

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure:	None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:	None
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Section 5 - Fire Fighting Measures

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Not available

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6 - Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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.

Section 7 - Handling and Storage

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Incompatible Materials: None known

Specific end use(s): No data available

Section 8 - Exposure Controls and Personal Protection

Control Parameters

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Progesterone

Zoetis OEL TWA 8-hr

30 µg/m³ Skin**Exposure Controls****Engineering Controls:**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate

Section 9 - Physical and Chemical Properties:

Physical State:	Solid	Color:	No data available
Odor:	No data available	Odor Threshold:	No data available
Molecular Formula:	Mixture		

Solvent Solubility: No data available

Water Solubility: No data available

pH: No data available

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available

Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

Progesterone

Odor Threshold: No data available

Predicted 7.4 Log D 4.04

Decomposition Temperature (°C): No data available

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Section 10 - Stability and Reactivity

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: None

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Conditions to Avoid:	None known
Incompatible Materials:	None known
Hazardous Decomposition Products:	No data available

Section 11 - Toxicological Information

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the active ingredient(s).

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

Progesterone

Rat Oral LD₅₀ >5000 mg/kg
Rat Sub-tenon injection (eye) LD₅₀ 327mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Progesterone

2 Year(s) Rabbit Intramuscular 13 mg/kg LOEL Female reproductive system
74 Week(s) Dog Subcutaneous 0.08-22.5 mg/day (increased dose) LOEL Female reproductive system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Progesterone

Reproductive & Fertility Rabbit No route specified Dose not specified Embryotoxicity
Embryo / Fetal Development Rat No route specified Dose not specified Not Teratogenic
Embryo / Fetal Development Monkey No route specified Dose not specified Not Teratogenic

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

Bacterial Mutagenicity (Ames) Negative
In Vivo Dominant Lethal Assay Mouse Negative
In Vivo Chromosome Aberration Rat Negative
In Vitro Chromosome Aberration Human Negative
In Vitro Cell Transformation Assay Rat Positive

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

Progesterone

2 Year(s) Rabbit Intramuscular 13 mg/kg NOEL Not carcinogenic
18 Month(s) Mouse Subcutaneous 0.059 mg/day LOEL Malignant tumors, Female reproductive system, Mammary Gland
40 Week(s) Rat Subcutaneous 200 mg/kg/day LOEL Malignant tumors, Liver
19 Week(s) Female Mouse Subcutaneous 25 mg/kg (5 days/week) LOEL Tumors, Mammary gland

Carcinogen Status: See below

Progesterone

IARC: Group 2B (Possibly Carcinogenic to Humans)
NTP: Reasonably Anticipated To Be a Human Carcinogen
OSHA: Listed

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Section 12 - Ecological Information

Environmental Overview:	Environmental properties have not been investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Progesterone	
Predicted	7.4 Log D 4.04
Mobility in Soil:	No data available

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities use a commercial waste disposal service.

Section 14 - Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under IATA, ADG or IMDG regulations.

Section 15 - Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Silicone rubber	
Australia (AICS):	Present
Nylon 66	
Australia (AICS):	Present
Progesterone	
Australia (AICS):	Present
Poison Schedule:	Schedule 5

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:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 th 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
NOS	Not otherwise specified

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NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

This version issued: 1 October 2016 and is valid for 5 years from this date

Supersedes: Revision issued November 2014

Revision History:

Date of Revision	Reason
30 Apr 2015	Update to GHS
01 Oct 2016	Corrections to GHS hazard classification, hazard and precautionary statements

Contact Points:

Zoetis Police and Fire Brigade:	1800 814 883 Dial 000
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If ineffective:

Dial Poisons Information Centre
(13 11 26 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

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