

SAFETY DATA SHEET



Revision date: 06-Jul-2015

Version: 1.0

Page 1 of 8

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Paccal Vet®-CA1

Trade Name: Paccal Vet®

Synonyms: Paccal Vet 60 mg; Paccal powder for solution

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary Antineoplastic

Restrictions on Use: For use only by (or on the order of) a licensed veterinarian

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Lyophilized powder

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2

Reproductive Toxicity: Category 1B

Reproductive Toxicity: Effects on or via lactation

Specific target organ systemic toxicity (repeated exposure): Category 1

EU Classification:

EU Indication of danger: Not determined

Label Elements

Signal Word: Danger

Hazard Statements: H360FD - May damage fertility. May damage the unborn child.
H362 - May cause harm to breast-fed children
H341 - Suspected of causing genetic defects
H372 - Causes damage to organs through prolonged or repeated exposure (bone marrow , blood and blood forming organs , gastrointestinal system , peripheral nervous system)

SAFETY DATA SHEET

Material Name: Paccal Vet®-CA1
Revision date: 06-Jul-2015

Page 2 of 8
Version: 1.0

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
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P263 - Avoid contact during pregnancy/while nursing
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P314 - Get medical attention/advice if you feel unwell
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Short Term: May cause eye irritation . Signs and symptoms might include redness, swelling, blurred vision or pain. May cause skin irritation. Signs and symptoms might include skin rash, itching, redness or swelling. May cause mucous membrane and respiratory tract irritation. May be toxic if swallowed. Systemic toxicity may also occur if inhaled in sufficient amounts. May be absorbed through mucous membranes and cause systemic effects.

Long Term: May cause blood and reproductive system effects ; may have the potential to produce effects on the developing fetus. This compound can cross the placenta in pregnant women. May cause effects on gastrointestinal system , bone marrow , blood forming organs .

Known Clinical Effects: Adverse effects associated with therapeutic use include decrease in blood pressure (hypotension), neutropenia, dizziness, infection, blood cell changes, flushing, skin rash, nausea, vomiting, inflammation of the mouth (stomatitis), sensory/motor nerve injury (peripheral neuropathy), loss of hair.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Paclitaxel	33069-62-4	Not Listed	Repr. Cat.2;R60-61 Mut. Cat.3;R68	Repr. 1B (H360FD) Mut. 2 (H341)	60 mg

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Excipients	Proprietary	Not Listed	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. For one or more ingredients, the chemical identity has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

SAFETY DATA SHEET

Material Name: Paccal Vet®-CA1
Revision date: 06-Jul-2015

Page 3 of 8
Version: 1.0

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:	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.
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
----------------------------	------

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:	Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Toxic Material! Ensure adequate ventilation. Avoid dust formation. Avoid contact with skin, eyes and clothing. Personnel must wear appropriate protective equipment (see Section 8). Prevent exposure by any route.

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 the spill if it is safe to do so. Avoid generating airborne dust. Collect spilled material by a method that controls dust generation. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean contaminated surface thoroughly. Prevent discharge to drains.
--	---

SAFETY DATA SHEET

Material Name: Paccal Vet®-CA1
Revision date: 06-Jul-2015

Page 4 of 8
Version: 1.0

Additional Consideration for Large Spills:

Provide adequate ventilation. Avoid generating airborne dust. Contain the source of the spill or leak and shut off all electrical equipment if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Prevent runoff from entering waterways or sewers. Prevent discharge to drains. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Additional Information:

It is recommended that areas handling the product have cytotoxic spill kits available. Spill kits should include impermeable body covering, shoe covers, gloves, goggles, approved respirator, disposable dust pan and scoop, absorbent towels, spill control pillows, disposable sponges, sharps container, disposable garbage bag, and a hazardous waste label.

7. HANDLING AND STORAGE

Precautions for Safe Handling

When handling, use proper personal protective equipment as specified in Section 8. Use with adequate ventilation. Restrict access to work area. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:

Store under refrigeration in closed container. Keep container tightly closed when not in use. Protect from heat and light. Keep away from direct sunlight. Keep out of reach of children.

Storage Temperature:

2-8°C (36-46°F)

Specific end use(s):

No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

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.

Paclitaxel

Zoetis OEB

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

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels to below the OEB range.

Personal Protective Equipment:

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

Hands:

Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses as minimum protection (goggles recommended).

Skin:

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

Respiratory protection:

Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.

SAFETY DATA SHEET

Material Name: Paccal Vet®-CA1
Revision date: 06-Jul-2015

Page 5 of 8
Version: 1.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Lyophilized powder	Color:	greenish/yellow
Odor:	Odorless	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	Soluble		
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		
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		

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Light sensitive. Avoid exposure to light, sunlight and elevated temperatures.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Toxic or corrosive oxides of carbon and nitrogen.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact , skin contact , inhalation

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

Paclitaxel

Rat IP LD50 32.5 mg/kg
Mouse IP LD50 128mg/kg
Mouse Intravenous LD50 12mg/kg

SAFETY DATA SHEET

Material Name: Paccal Vet®-CA1
Revision date: 06-Jul-2015

Page 6 of 8
Version: 1.0

11. TOXICOLOGICAL INFORMATION

Inhalation Acute Toxicity May be irritating and / or toxic if inhaled. Symptoms may include coughing, difficulty breathing and respiratory distress.

Ingestion Acute Toxicity May be toxic if swallowed.

Irritation / Sensitization Comments: May cause eye irritation.

Skin Irritation / Sensitization May cause skin irritation.

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

Paclitaxel

6 Month(s) Rat Intravenous 1 mg/kg/day NOAEL Blood forming organs, Bone marrow, Thymus, Spleen

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

Paclitaxel

Fertility and Embryonic Development Rat Intravenous 1 mg/kg/day NOAEL Fetotoxicity, Maternal toxicity, Paternal toxicity

Embryo / Fetal Development Rat Intravenous 0.3 mg/kg/day NOAEL Developmental toxicity

Embryo / Fetal Development Rabbit Intravenous 1 mg/kg/day NOAEL Fetotoxicity, Maternal Toxicity

Prenatal & Postnatal Development Rat Intravenous 0.3 mg/kg/day NOAEL Neonatal toxicity, Maternal Toxicity

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

Paclitaxel

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative (with activation , without activation)

In Vitro Mouse Lymphoma Assay Mouse Positive

In Vitro Chromosome Aberration Human Lymphocytes Positive

In Vivo Micronucleus Mouse Positive

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Incineration is the recommended method of disposal for this material. If no on-site incinerator is available, dispose of material in a licensed commercial chemical incinerator.

SAFETY DATA SHEET

Material Name: Paccal Vet®-CA1
Revision date: 06-Jul-2015

Page 7 of 8
Version: 1.0

14. TRANSPORT INFORMATION

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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Excipients

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

Paclitaxel

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

developmental toxicity initial date 8/26/97

female reproductive toxicity 8/26/97

male reproductive toxicity initial date 8/26/97

Schedule 4

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

Not Listed

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.

Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects

SAFETY DATA SHEET

Material Name: Paccal Vet®-CA1
Revision date: 06-Jul-2015

Page 8 of 8
Version: 1.0

Toxic to Reproduction: Category 2

Mutagenic: Category 3

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

R68 - Possible risks of irreversible effects.

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

Reasons for Revision: New data sheet.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

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.

End of Safety Data Sheet