

SAFETY DATA SHEET



1. Identification

Product identifier	PALLADIA
Other means of identification	
Synonyms	Palladia 50MG/15MG/10MG * Toceranib Phosphate Tablets
Recommended use	Veterinary anti-neoplastic agent
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison & Drug Safety	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium
Telephone	+32 10 808080
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPRecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity (the unborn child)	Category 1B
	Specific target organ toxicity, repeated exposure	Category 1 (blood system, digestive system)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	May damage the unborn child. Causes damage to organs (blood system, digestive system) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) May form combustible dust concentrations in air.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Toceranib (as Toceranib phosphate)		874819-74-6	10, 15, or 50 mg***
Colloidal silicon dioxide		7631-86-9	*
Magnesium stearate		557-04-0	*
Microcrystalline cellulose		9004-34-6	*

Composition comments *** per tablet/capsule/lozenge/suppository
* Non-hazardous Ingredients
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. The full text for all H-statements is displayed in section 16.

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

Skin contact Remove contaminated clothing. Wash off immediately with soap and plenty of water. Get medical advice/attention if you feel unwell. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.

Eye contact Do not rub eyes. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Call a physician or poison control center immediately.

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

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Prolonged exposure may cause chronic effects. May cause reproductive effects. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

General information 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. For personal protection, see section 8 of the SDS.

5. Fire-fighting measures

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 Fine particles (such as dust and mists) may fuel fires/explosions.

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

Fire fighting equipment/instructions Use water spray to cool unopened containers.

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

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS. Do not get in eyes, on skin, or on clothing.

Methods and materials for containment and cleaning up

ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Avoid dust formation. Ensure adequate ventilation.

Large Spills: Stop the flow of material, if this is without risk. Clean surface thoroughly to remove residual contamination.

Small Spills: Clean surface thoroughly to remove residual contamination. 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. Wear personal protective equipment. Prevent release to the environment.

Environmental precautions

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

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. Avoid dust formation. Do not taste or swallow. Do not get this material on clothing. Use this product with adequate ventilation. Avoid contact with skin. Avoid prolonged exposure. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Wash contaminated clothing before reuse. Observe good industrial hygiene practices. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). @ 15-30°C (59-86°F)..

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis

Components	Type	Value
Toceranib (as Toceranib phosphate) (CAS 874819-74-6)	TWA	10 µg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		0.8 mg/m3	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Magnesium stearate (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Colloidal silicon dioxide (CAS 7631-86-9)	TWA	6 mg/m3	
Microcrystalline cellulose (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values	No biological exposure limits noted for the ingredient(s).
Control banding approach	Not available.
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. Ensure adequate ventilation, especially in confined areas.
Individual protection measures, such as personal protective equipment	
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. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn.
Thermal hazards	Not applicable.
General hygiene considerations	Observe any medical surveillance requirements. 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	Tablets
Physical state	Solid.
Form	Solid.
Color	Orange. or Blue. or Red.
Odor	Not available.
Odor 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 available.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor 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 information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

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 Keep away from heat, spark, open flames and other sources of ignition. Protect from sunlight. Moisture. Contact with incompatible materials.

Incompatible materials Strong oxidizing agents. Fluorine.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Carbon oxides. Nitrogen oxides (NOx). May include oxides of phosphorus. Hydrogen fluoride.

11. Toxicological information

Information on likely routes of exposure

Inhalation Prolonged inhalation may be harmful. 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.

Microcrystalline cellulose Species: Rabbit
Severity: Non-irritating

Toceranib (as Toceranib phosphate) Species: Rabbit
Severity: Non-irritating

Eye contact Direct contact with eyes may cause temporary irritation.

Toceranib (as Toceranib phosphate) Species: Rabbit
Severity: Minimal

Microcrystalline cellulose Species: Rabbit
Severity: Non-irritating

Ingestion Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause reproductive effects. Prolonged exposure may cause chronic effects. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Information on toxicological effects

Acute toxicity May be harmful in contact with skin. May be harmful if swallowed.

Components	Species	Test Results
Colloidal silicon dioxide (CAS 7631-86-9)		
Acute		
Oral		
LD50	Rat	> 22500 mg/kg
Magnesium stearate (CAS 557-04-0)		
Acute		
Inhalation		
LC50	Rat	> 2000 mg/m3
Oral		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
Microcrystalline cellulose (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Toceranib (as Toceranib phosphate) (CAS 874819-74-6)		
Acute		
Oral		
	Rat	2500 mg/kg (Minimum Lethal Dose)
Subacute		
Oral		
LOAEL	Dog	2.5 mg/kg/day, 7 days (Target organ(s): Gastrointestinal system)
	Rat	10 mg/kg/day, 14 days (Target organ(s): Liver, Lymphatic system, Pancreas, Adrenal gland)
NOAEL	Dog	< 50 mg/kg/day, 8 days (Target organ(s): Gastrointestinal system, Pancreas)
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Toceranib (as Toceranib phosphate)	Species: Rabbit	Severity: Non-irritating
Serious eye damage/eye irritation		
Direct contact with eyes may cause temporary irritation.		
Eye Contact		
Toceranib (as Toceranib phosphate)	Species: Rabbit	Severity: Minimal
Microcrystalline cellulose	Species: Rabbit	Severity: Non-irritating
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Skin sensitization		
Toceranib (as Toceranib phosphate)	LLNA	Species: Mouse Severity: Negative
Germ cell mutagenicity		
No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.		
Mutagenicity		
Toceranib (as Toceranib phosphate)	In Vitro Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli	
	In Vitro Chromosome Aberration Result: Negative Species: Human Lymphocytes	
	In Vivo Micronucleus Result: Negative Species: Rat	
Carcinogenicity	Due to partial or complete lack of data the classification is not possible.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Colloidal silicon dioxide (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.	

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity	May damage the unborn child.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Causes damage to organs (blood system, digestive system) through prolonged or repeated exposure.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	Prolonged inhalation may be harmful. Causes damage to organs through prolonged or repeated exposure.

12. Ecological information

Ecotoxicity	Avoid release to the 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.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
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 instructions	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. 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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	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 applicable.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
Toxic Substances Control Act (TSCA)	One or more components of the mixture are not on the TSCA 8(b) inventory or are designated "inactive".
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical Yes**Classified hazard categories** Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****California Proposition 65**California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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
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, including date of preparation or last revision

Issue date 05-24-2017
Revision date 04-13-2023
Version # 02

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Revision information This document has undergone significant changes and should be reviewed in its entirety.