

Safety Data Sheet

Product Name: Trimeprazine with Prednisolone Tablets
Strength : Trimeprazine, 5 mg, and prednisolone, 2 mg
Emergency Overview

Revision No.: 00

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

SECTION 1: IDENTIFICATION

Product Name: Trimeprazine with Prednisolone Tablets

Formula: C₁₈H₂₂N₂S · C₄H₆O₆ (Trimeprazine + Tartaric Acid)
Prednisolone: C₂₁H₂₈O₅

Chemical Name: Trimeprazine Tartrate: 10-(3-Dimethylaminopropyl) phenothiazine hydrogen tartrate
Prednisolone: 11 β ,17 α ,21-Trihydroxypregna-1,4-diene-3,20-dione

Molecular Weight: Trimeprazine Tartrate: 447.53 g/mol, Prednisolone: 360.44 g/mol.

Description: Each tablet contains Trimeprazine tartrate (USP) 10-[3-(Dimethylamino)-2-methylpropyl]phenothiazine tartrate (2:1) equivalent to Trimeprazine, 5 mg, and Prednisolone, 2 mg.
Action: The exclusive Trimeprazine with Prednisolone formula combines the antipruritic and antitussive action of Trimeprazine with the anti-inflammatory action of prednisolone. A therapeutic effect is attained by administering the tablets twice daily.

Dosage forms and strengths: Each tablet contains Trimeprazine tartrate (USP) 10-[3-(Dimethylamino)-2-methylpropyl]phenothiazine tartrate (2:1) equivalent to Trimeprazine, 5 mg, and Prednisolone, 2 mg. Supplied as 100- and 1000-tablet bottles.

Product name	Strength	Pack count	NDC Number
Trimeprazine with Prednisolone Tablets	Trimeprazine 5 mg Prednisolone 2 mg	HDPE bottle of 100 tablets	8611703207
		HDPE bottle of 1000 tablets	8611703213

Manufacturer/supplier identification

Company ZyduS Animal Health and Investments Limited,
Ahmedabad, India
Contact for information Tel.: +91 2717-683954
Emergency Telephone No Tel.: +91 2717-683961
Distributed by: ZyVet Animal Health Inc.
Pennington, NJ 08534

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SECTION 2: HAZARD (S) IDENTIFICATION

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



Signal word	Danger
Hazard statement	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May damage the unborn child. Causes damage to organs (heart). Causes damage to organs (nervous 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/vapours/spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection.
Response	If exposed or concerned: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

SECTION 3: INFORMATION ON THE INGREDIENTS

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Acacia		9000-01-5	<5
Cellulose		9004-34-6	<5
Magnesium stearate		557-04-0	<1
Calcium sulfate		7778-18-9	
Corn Starch		9005-25-8	
Prednisolone (Anhydrous)		50-24-8	2 mg
Trimeprazine Tartrate		4330-99-8	5 mg

Composition comments: In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

SECTION 4: FIRST AID MEASURES

Inhalation	Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. If breathing is difficult, trained personnel should give oxygen.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

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Most important symptoms/effects, acute and delayed

Fatigue. Dizziness. Narcosis. Behavioral changes. Decrease in motor functions. Difficulty in breathing. May cause decreases in blood pressure and other cardiac effects. Prolonged exposure may cause chronic effects. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances.

Indication of immediate medical attention and special treatment needed General information

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

SECTION 5: FIRE FIGHTING MEASURES

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
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 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.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Remove sources of ignition. Wear appropriate protective equipment and clothing during clean-up.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

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.

Environmental precautions

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

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling	Use this product with adequate ventilation. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.
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Conditions for safe storage, including any incompatibilities

Store locked up. Keep tightly closed in a dry, cool and well-ventilated place. @ 15 - 25°C (59 -77°F). Keep away from heat and sources of ignition. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

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SECTION 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.

Components	Type	Value
Prednisolone (Anhydrous) (CAS 50-24-8)	TWA	5 µg/m ³

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

Components	Type	Value	Form
Calcium Sulphate (CAS 7778-18-9)	PEL	5 mg/m ³	Respirable fraction.
Cellulose (CAS 9004-34-6)	PEL	15 mg/m ³	Total dust.
		5 mg/m ³	Respirable fraction.
Corn Starch (CAS 9005-25-8)	PEL	15 mg/m ³	Total dust.
		5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Calcium sulfate (CAS 7778-18-9)	TWA	10 mg/m ³	Inhalable fraction.
Cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	
Corn Starch (CAS 9005-25-8)	TWA	10 mg/m ³	
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Calcium sulfate (CAS 7778-18-9)	TWA	5 mg/m ³	Respirable.
Cellulose (CAS 9004-34-6)	TWA	10 mg/m ³ Total	Respirable.
		5 mg/m ³	
Corn Starch (CAS 9005-25-8)	TWA	10 mg/m ³ Total	Respirable.
		5 mg/m ³	
		10 mg/m ³ Total	

Biological limit values No biological exposure limits noted for the ingredient(s).
Exposure guidelines OEL Additional Information: Skin (May be absorbed through the skin and cause systemic effects.)

Control banding approach

Trimeprazine tartrate: Zoetis OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

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 Impervious gloves. Wear impervious, disposable gloves as minimum protection (double recommended).
Other Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment. Respirator must be worn if exposed to dust. 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 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.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Tablet.
Physical state	Solid.
Form	Solid.
Color	Not available.
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	Flammability limit – lower (%) Not available.
Flammability limit – upper (%)	Not available.
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.

SECTION 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	Contact with incompatible materials. Avoid heat, sparks, open flames and other ignition sources.
Incompatible materials	Aluminum. Phosphorus. Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

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SECTION 11: TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation may be harmful.

Skin contact Prolonged skin contact may cause temporary irritation. May be absorbed through the skin and cause systemic effects.

Eye contact Direct contact with eyes may cause temporary irritation.

Acacia
Species: Rabbit
Severity: Severe

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

Fatigue. Dizziness. Narcosis. Behavioral changes. Decrease in motor functions. Difficulty in breathing. May cause decreases in blood pressure and other cardiac effects. Prolonged exposure may cause chronic effects. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances.

Information on toxicological effects

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

Product	Species	Test Results
Tablets Acute Oral ATE		5000 mg/kg

Components	Species	Test Results
Cellulose (CAS 9004-34-6) Dermal Acute LD50	Rabbit	> 2000 mg/kg
Inhalation LC50	Rat	> 5.05 mg/l/4h
Oral LD50	Rat	> 5000 mg/kg
Magnesium stearate (CAS 557-04-0) Inhalation Acute LC50	Rat	> 2000 mg/m3
Oral LD50	Rat	> 2000 mg/kg
Prednisolone (Anhydrous) (CAS 50-24-8) Acute Intraperitoneal LD50	Mouse	65 mg/kg
Oral LD50	Mouse	1680 mg/kg
Chronic Oral LOAEL	Guinea Pig	1 mg/kg/day, 24 weeks (Target organs: Bone, Blood)
Subacute Oral LOAEL	Dog	2.5 mg/kg/day, 6 weeks (Target organs: Adrenal gland, Liver)
	Rat	10.1 mg/kg, 4 days (Target organs: None identified)

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Trimeprazine Tartrate (CAS 4330-99-8)

Acute

Intravenous

LD50 Rat 35 mg/kg

Oral

LD50 Mouse 300 mg/kg

Rat 210 mg/kg

Skin corrosion/irritation

Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation

Direct contact with eyes may cause temporary irritation.

Eye Contact

Acacia

Species: Rabbit

Severity: Severe

Respiratory or skin sensitization

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization

This product is not expected to cause skin sensitization.

Germ cell mutagenicity

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

Mutagenicity

Prednisolone (Anhydrous)

Cytogenetics

Result: Negative

Species: Human Lymphocytes

In Vivo Mammalian Cell Mutagenicity

Result: Negative

Species: Mouse Lymphoma

Mutagenicity

Prednisolone (Anhydrous)

Sister Chromatid Exchange

Result: Negative

Species: Human Lymphocytes

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

May damage the unborn child.

Developmental effects

Prednisolone (Anhydrous)

0.5 mg/day Embryo / Fetal Development, Teratogenic

Result: LOEL

Species: Mouse

Organ: No route specified

2.5 mg/kg Embryo / Fetal Development, Teratogenic

Result: LOEL

Species: Rat

Organ: Subcutaneous

Reproductivity

Prednisolone (Anhydrous)

250 - 600 mg/kg/day Reproductive & Fertility, Teratogenic

Result: LOAEL

Species: Rat

Organ: Oral

Specific target organ toxicity single exposure

Causes damage to organs (heart).

Specific target organ toxicity repeated exposure

Causes damage to organs (nervous system) through prolonged or repeated exposure.

Aspiration hazard

Not an aspiration hazard.

Chronic effects

Prolonged exposure may cause chronic effects.

SECTION 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.

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Components	Species	Test Results
Calcium sulfate (CAS 7778-18-9)		
Aquatic		
Fish LC50	Fathead minnow (Pimephales promelas)	> 1970 mg/l, 96 hours
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.	

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal instructions

Avoid release to the environment. 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 None known.

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 (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

SECTION 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 Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

SECTION 15: REGULATORY INFORMATION

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard - Yes

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Delayed Hazard - Yes

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

Hazard categories

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous No chemical

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 Not regulated.

(SDWA)

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
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
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).

SECTION 16: OTHER INFORMATION

References: Nil.

Issue date: 10-06-2024

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product