

SAFETY DATA SHEETS

This SDS packet was issued with item:

078949893

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078949898 078949899 078949900



Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.19.2024

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Calmera (clomipramine) Tablets 5mg, 20mg, 40mg, & 80mg | 30s (RX)

SECTION 1: Identification

Product Identifier

Product Name: Calmera (clomipramine) Tablets 5mg, 20mg, 40mg, & 80mg | 30s (RX)

Product code: 078949893, 078949898, 078949899, 078949900

Recommended Use of the Product and Restriction on Use

Relevant Identified Uses: To treat separation anxiety in dogs greater than 6 months of age, inappropriate barking or destructive behavior, as well as inappropriate elimination.

Uses Advised Against: Any use other than recommended above.

Reasons Why Uses Advised Against: Not determined or not applicable.

Manufacturer or Supplier Details

Supplier:

United States

Aspen Veterinary Resources, LTD.

3155 W. Heartland Drive

Liberty, MO 64068

1-800-792-1238

Emergency Telephone Number:

United States

CHEMTREC

Within USA and Canada: 1-800-424-9300 (24 hours)

Outside USA and Canada: +1-703-527-3887 (24 hours)

SECTION 2: Hazard(s) Identification

GHS Classification: Not a hazardous substance or mixture

Label elements

Hazard Pictograms: None

Signal Word: None

Hazard statements: None

Precautionary Statements:

P102 Keep out of reach of children

Hazards Not Otherwise Classified:

Health Hazards: In the workplace, exposure via inhalation and eye or skin contact may cause irritation.

Overdose in humans causes anticholinergic effects including effects on the central nervous (e.g., convulsions) and cardiovascular (e.g., arrhythmia, tachycardia) systems.

Flammability Hazards: This product requires substantial pre-heating before ignition occurs. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides (NOx), and hydrogen chloride gas).

Reactivity Hazards: This product is not reactive.

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Environmental Hazards: Release of large quantity to the environment may be harmful to plants and animals and aquatic organisms.

Emergency Recommendations: Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

SECTION 3: Composition/Information on Ingredients

Identification	Name	Weight %
CAS Number: 17321-77-6	Clomipramine hydrochloride*	99
CAS Number: 112945-52-5	Silica, amorphous, fumed, cryst.-free	<0.1
CAS Number: 9003-39-8	2-Pyrrolidinone, 1-ethenyl-, homopolymer	<0.1
CAS Number: 64044-51-5	lactose monohydrate	<0.1
CAS Number: 557-04-0	Magnesium distearate	<0.1
CAS Number: 9004-34-6	Cellulose	<0.1
CAS Number: 616-45-5	2-Pyrrolidinone	<0.1

Additional Information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200).

* Active ingredient

SECTION 4: First Aid Measures

Description of First Aid Measures

General Notes:

Show this Safety Data Sheet to the doctor in attendance.

After Inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. If respiratory symptoms develop or persist, seek medical advice/attention.

After Skin Contact:

Wash affected area with plenty of soap and water. Remove contaminated clothing and launder before reuse. If skin irritation develops or persists, seek medical advice/attention.

After Eye Contact:

Immediately rinse eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 15 minutes. If eye irritation develops or persists, seek medical advice/attention.

After Swallowing:

This product is intended to be swallowed; however, if an overdose occurs CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, victim should drink up to three glasses of water. Do not induce

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vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention.

Most Important Symptoms and Effects, Both Acute and Delayed

Acute Symptoms and Effects:

Not determined or not applicable.

Delayed Symptoms and Effects:

Not determined or not applicable.

Immediate Medical Attention and Special Treatment

Specific Treatment:

Not determined or not applicable.

Notes for the Doctor:

Treat symptomatically.

SECTION 5: Firefighting Measures

Extinguishing Media

Suitable Extinguishing Media:

Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.

Unsuitable Extinguishing Media:

None known.

Specific Hazards During Fire-Fighting:

This product must be substantially pre-heated before ignition can occur. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including aluminum, carbon, sodium, sulfur, magnesium, and nitrogen oxides, and hydrogen chloride).

Special Protective Equipment for Firefighters:

Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fireresponse equipment should be decontaminated with soapy water and thoroughly rinsed before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

SECTION 6: Accidental Release Measures

Personal Precautions, Protective Equipment, and Emergency Procedures:

Small Spills/Spills in Hoods: Personnel wearing nitrile or other appropriate gloves, lab coat or other protective clothing and eye protection should immediately clean incidental spills of less than 5 mL.

Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves and protective clothing. When there is any danger of airborne dusts being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

Environmental Precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways.

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Discharge into the environment must be avoided.

Methods and Material for Containment and Cleaning Up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to Other Sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and Storage

Precautions for Safe Handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Conditions for Safe Storage, Including Any Incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).
Recommended Storage Temperature: 20-25°C (68-77°F).
SPECIFIC END USE: This product is an animal pharmaceutical.

SECTION 8: Exposure Controls/Personal Protection

Only those substances with limit values have been included below.

Occupational Exposure Limit Values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
NIOSH	Silica, amorphous, fumed, cryst.-free	112945-52-5	REL-TWA: 6 mg/m ³ (Silica, amorphous [up to 19 hr])
	Silica, amorphous, fumed, cryst.-free	112945-52-5	IDLH: 3000 mg/m ³ (Silica, amorphous)
	Cellulose	9004-34-6	REL-TWA: 10 mg/m ³ ([up to 10 hr] Total)
	Cellulose	9004-34-6	REL-TWA: 5 mg/m ³ ([up to 10 hr] Respirable)
OSHA	Silica, amorphous, fumed, cryst.-free	112945-52-5	8-Hour TWA: 0.8 mg/m ³ (Silica: Amorphous, including natural diatomaceous earth)
	Cellulose	9004-34-6	8-Hour TWA-PEL: 5 mg/m ³ (Respirable fraction)
	Cellulose	9004-34-6	8-Hour TWA-PEL: 15 mg/m ³ (Total dust)
United States(California)	Silica, amorphous, fumed, cryst.-free	112945-52-5	8-Hour TWA: 10 mg/m ³ (Particulates not otherwise regulated, total dust)
	Silica, amorphous, fumed, cryst.-free	112945-52-5	8-Hour TWA: 5 mg/m ³ (Particulates not otherwise regulated, respirable fraction)
	Magnesium distearate	557-04-0	PEL: 10 mg/m ³

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Country (Legal Basis)	Substance	Identifier	Permissible concentration
	Cellulose	9004-34-6	8-Hour TWA-PEL: 10 mg/m ³ (Particulate not otherwise regulated, total dust)
	Cellulose	9004-34-6	8-Hour TWA-PEL: 5 mg/m ³ (Particulate not otherwise regulated, respirable fraction)
ACGIH	Silica, amorphous, fumed, cryst.-free	112945-52-5	8-Hour TWA: 3 mg/m ³ (Particles, insoluble or poorly soluble, N.O.S, respirable)
	Silica, amorphous, fumed, cryst.-free	112945-52-5	8-Hour TWA: 10 mg/m ³ (Particles, insoluble or poorly soluble, N.O.S, inhalable)
	Magnesium distearate	557-04-0	8-Hour TWA: 10 mg/m ³ (Stearates, inhalable fraction)
	Magnesium distearate	557-04-0	8-Hour TWA: 3 mg/m ³ (Stearates, respirable fraction)
	Cellulose	9004-34-6	8-Hour TWA: 10 mg/m ³

Biological Limit Values:

No biological exposure limits noted for the ingredient(s).

Information on Monitoring Procedures:

Not determined or not applicable.

Appropriate Engineering Controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal Protection Equipment

Eye and Face Protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and Body Protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory Protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General Hygienic Measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and Chemical Properties

Information on Basic Physical and Chemical Properties

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Appearance	Solid; light brown speckled modified capsule shaped tablet
Odor	Meaty
Odor threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Evaporation rate	Not determined or not available.
Flammability (solid, gas)	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.
Vapor density	Not determined or not available.
Density	Not determined or not available.
Relative density	Not determined or not available.
Solubilities	Not determined or not available.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Dynamic viscosity	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Explosive properties	Not determined or not available.
Oxidizing properties	Not determined or not available.

SECTION 10: Stability and Reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Chemical Stability:

Stable under recommended handling and storage conditions.

Possibility of Hazardous Reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to Avoid:

Exposure to or contact with extreme temperatures, incompatible chemicals.

Incompatible Materials:

Strong oxidizing agents, and strong acids.

Hazardous Decomposition Products:

Products of thermal decomposition may include carbon, sodium, sulfur, magnesium, and nitrogen oxides, and hydrogen chloride. Hydrolysis: None known.

SECTION 11: Toxicological Information

Acute Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data:

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Name	Route	Result
Clomipramine hydrochloride*	Oral ATE	LD50 Rat: 500 mg/kg
	Dermal ATE	LD50 Rabbit: 1100 mg/kg
	Inhalation ATE	LC50 Rat: 11 mg/L (4hr [vapour])
Silica, amorphous, fumed, cryst.-free	oral	LD50 rat: 3160 mg/kg
Cellulose	dermal	LD50 Rabbit: > 2000 mg/kg
	inhalation	LC50 Rat: > 5.8 mg/L (4 hr [dust])
	oral	LD50 Rat: > 5000 mg/kg
2-Pyrrolidinone	oral	LD50 Rat: >2000 mg/kg
	dermal	LD50 Rabbit: >2000 mg/kg

Skin Corrosion/Irritation

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data:

Name	Result
Clomipramine hydrochloride*	Causes skin irritation.
Silica, amorphous, fumed, cryst.-free	Causes skin irritation.

Serious Eye Damage/Irritation

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data:

Name	Result
Clomipramine hydrochloride*	Causes serious eye irritation.
Silica, amorphous, fumed, cryst.-free	Causes serious eye irritation.
2-Pyrrolidinone	Causes serious eye irritation.

Respiratory or Skin Sensitization

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data: No data available.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data: No data available.

International Agency for Research on Cancer (IARC):

Name	Classification
Silica, amorphous, fumed, cryst.-free	Group 3

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Name	Classification
2-Pyrrolidinone, 1-ethenyl-, homopolymer	Group 3

National Toxicology Program (NTP): None of the ingredients are listed.

OSHA Carcinogens:

Ingredient Name	CAS	OSHA Carcinogens Status
Cellulose	9004-34-6	Yes

Germ Cell Mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data: No data available.

Reproductive Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data:

Name	Result
2-Pyrrolidinone	May damage the unborn child.

Specific Target Organ Toxicity (Single Exposure)

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data:

Name	Result
Clomipramine hydrochloride*	May cause respiratory irritation.
Silica, amorphous, fumed, cryst.-free	May cause respiratory irritation.

Specific Target Organ Toxicity (Repeated Exposure)

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data: No data available.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data:

No data available.

Substance Data: No data available.

Information on Likely Routes of Exposure:

Skin contact, ingestion, inhalation, eye contact

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:

See section 4 of this SDS.

Other Information:

No data available.

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SECTION 12: Ecological Information

Acute (Short-Term) Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data:

Name	Result
2-Pyrrolidinone	Fish LC50 Danio rerio: > 4600 - 10,000 mg/L (96 hr)
	Aquatic Invertebrates EC50 Daphnia magna: >500 mg/L (48 hr [mobility])
	Aquatic Plants EC50 Desmodemus subspicatus: >500 mg/L (72 hr [growth rate])

Chronic (Long-Term) Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product Data: No data available.

Substance Data: No data available.

Persistence and Degradability

Product Data: No data available.

Substance Data:

Name	Result
2-Pyrrolidinone	The substance is readily biodegradable. 73% degradation in water, measured by O2 consumption, after 28 days.

Bioaccumulative Potential

Product Data: No data available.

Substance Data:

Name	Result
2-Pyrrolidinone	The substance is very low potential for bioaccumulation in aquatic organisms [BCF (aquatic species): 3.16 L/kg ww].

Mobility in Soil

Product Data: No data available.

Substance Data:

Name	Result
2-Pyrrolidinone	The substance is highly mobile in soil with a low potential for adsorption to soil and sediment [Koc at 20 °C: 7.377, QSAR].

Results of PBT and vPvB assessment

Product Data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance Data:

PBT assessment:

2-Pyrrolidinone	The substance is not PBT.
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vPvB assessment:

2-Pyrrolidinone	The substance is not vPvB.
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Other Adverse Effects: No data available.

SECTION 13: Disposal Considerations

Disposal Methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to

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applicable regulatory agencies. Dispose of in accordance with all applicable local, regional, state and federal regulations.

Contaminated packages:

Not determined or not applicable.

SECTION 14: Transport Information

United States Transportation of Dangerous Goods (49 CFR DOT)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

International Maritime Dangerous Goods (IMDG)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

SECTION 15: Regulatory Information

United States Regulations

Inventory Listing (TSCA): All ingredients are listed-active or exempt.

Significant New Use Rule (TSCA Section 5): None of the ingredients are listed.

Export Notification under TSCA Section 12(b): None of the ingredients are listed.

SARA Section 302 Extremely Hazardous Substances: None of the ingredients are listed.

SARA Section 313 Toxic Chemicals: None of the ingredients are listed.

CERCLA: None of the ingredients are listed.

RCRA: None of the ingredients are listed.

Section 112(r) of the Clean Air Act (CAA): None of the ingredients are listed.

Massachusetts Right to Know:

9004-34-6	Cellulose	Listed
616-45-5	2-Pyrrolidinone	Listed

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New Jersey Right to Know:

9004-34-6	Cellulose	Listed
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New York Right to Know: None of the ingredients are listed.

Pennsylvania Right to Know:

9004-34-6	Cellulose	Listed
616-45-5	2-Pyrrolidinone	Listed

California Proposition 65: None of the ingredients are listed.

Additional information: Not determined.

SECTION 16: Other Information

Abbreviations and Acronyms: None

Disclaimer:

This product has been classified in accordance with OSHA HCS 2012 guidelines. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

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End of Safety Data Sheet