

SAFETY DATA SHEETS

This SDS packet was issued with item:

078952305

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

078951701 078951952 078952304

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 01.08.2024

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Mometavet

SECTION 1: Identification

Product Identifier

Product Name: Mometavet

Synonyms: Gentamicin sulfate, USP; Mometasone furoate anhydrous; and Clotrimazole, USP, Otic suspension for dogs.

Recommended Use of the Product and Restriction on Use

Relevant Identified Uses: VETERINARY USE: Treatment of otitis externa in dogs.

Uses Advised Against: Not for human use.

Reasons Why Uses Advised Against: Veterinary product.

Manufacturer or Supplier Details

Supplier:

United States

Dechra Veterinary Products
Dechra Veterinary 7015 College Blvd Suite 525
Overland Park, KS 66211
866-933-2472
support@dechra.com
www.dechra-us.com

Emergency Telephone Number:

United States

ASPCA Poison Control Center
1-888-426-4435

SECTION 2: Hazard(s) Identification

GHS Classification:

Respiratory sensitization, category 1
Skin sensitization, category 1
Reproductive toxicity, category 1A
Aspiration hazard, category 1

Label elements

Hazard Pictograms:



Signal Word: Danger

Hazard statements:

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 May cause an allergic skin reaction
H360 May damage fertility or the unborn child.
H304 May be fatal if swallowed and enters airways

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Precautionary Statements:

- P201 Obtain special instructions before use
P202 Do not handle until all safety precautions have been read and understood
P261 Do not breathe mist, vapors or spray.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
P284 In case of inadequate ventilation wear respiratory protection.
P272 Contaminated work clothing must not be allowed out of the workplace
P304+P341 IF INHALED: If breathing is **difficult**, remove victim to fresh air and keep at rest in a position comfortable for breathing
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
P302+P352 IF ON SKIN: Wash with plenty of water and soap.
P363 Wash contaminated clothing before reuse
P321 **Specific** treatment (see Sections 4-8 of this SDS and any supplemental information on the product label).
P333+P313 If skin irritation or rash occurs: Get medical advice/attention
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or a doctor.
P331 Do NOT induce vomiting
P308+P313 IF exposed or concerned: Get medical advice/attention
P405 Store locked up
P501 Dispose of contents and container in accordance with local regulations.

Hazards Not Otherwise Classified: None

SECTION 3: Composition/Information on Ingredients

Identification	Name	Weight %
CAS Number: 8042-47-5	Mineral oil	>90
CAS Number: 25322-68-3	Polyethylene	1-5
CAS Number: 23593-75-1	Clotrimazole	<1
CAS Number: 1405-41-0	Gentamicin sulfate	<0.5
CAS Number: 83919-23-7	Mometasone furoate	<0.2

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).

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. Keep person at rest. If breathing is **difficult**, **administer oxygen**. If breathing has stopped, provide artificial respiration. If experiencing respiratory symptoms, seek medical advice/attention.

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After Skin Contact:

Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

After Eye Contact:

Rinse eyes with plenty of water for several minutes. Remove contact lenses if present and easy to do so. Protect unexposed eye. If symptoms develop or persist, seek medical advice/attention.

After Swallowing:

This product presents an aspiration hazard. If aspiration is suspected, seek emergency medical treatment. If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most Important Symptoms and Effects, Both Acute and Delayed

Acute Symptoms and Effects:

Inhalation exposure may cause allergy, asthma symptoms or breathing **difficulties**. Symptoms may include cough, chronic phlegm, shortness of breath, wheezing and chest tightness. Symptoms may be delayed.

Dermal exposure may cause an allergic skin reaction. Symptoms may include irritation, redness, pain, **rash, inflammation**, itching, burning and dermatitis.

May be fatal if swallowed and enters airways. Aspiration may cause pulmonary edema and pneumonitis. Symptoms may include shortness of breath, dry cough and irritation of the nose, eyes, lips, mouth and throat.

Delayed Symptoms and Effects:

Effects are dependent on exposure (dose, concentration, contact time).

Long term exposure may **affect fertility**. **Symptoms** include, but are not limited to: menstrual problems, altered sexual behavior/fertility/ and pregnancy outcome. Long term exposure may also **affect** development of the unborn child. Symptoms include, but are not limited to: intrauterine growth retardation, pre-term birth, birth defects and postnatal death.

Symptoms of pulmonary edema may be delayed.

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:

Water mist/fog, carbon dioxide, dry chemical or alcohol resistant foam.

Unsuitable Extinguishing Media:

Do not use water jet.

Specific Hazards During Fire-Fighting:

Thermal decomposition may produce irritating/toxic fumes/gases.

Special Protective Equipment for Firefighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

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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:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Do not get on skin, eyes or on clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling. Remove contaminated clothing and launder before reuse.

Environmental Precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. 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). Do not store above 25°C (77°F). Store upright and out of direct sunlight.

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
ACGIH	Mineral oil	8042-47-5	8-Hour TWA: 5 mg/m ³ (Oil mists, mineral [Pure, highly and severely refined, inhalable fraction])
NIOSH	Mineral oil	8042-47-5	REL-TWA: 5 mg/m ³ (up to 10 hr; Oil mists, mineral)

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Country (Legal Basis)	Substance	Identifier	Permissible concentration
	Mineral oil	8042-47-5	IDLH: 2500 mg/m ³ (Oil mists, mineral)
	Mineral oil	8042-47-5	15-Minute STEL: 10 mg/m ³ (Oil mist, mineral)
OSHA	Mineral oil	8042-47-5	8-Hour TWA-PEL: 5 mg/m ³ (Oil mists, mineral)
United States(California)	Mineral oil	8042-47-5	8-Hour TWA-PEL: 5 mg/m ³ (Oil mists, mineral [particulate])
WEEL	Polyethylene	25322-68-3	8-Hour TWA: 10 mg/m ³ (molecular weight >200 aerosol)

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. Use a positive pressure air supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection.

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

Appearance	White to off-white suspension, viscous
Odor	Oil odor

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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)	Under normal conditions of use, this material does not present a significant fire or explosion hazard.
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	Miscible in water
Partition coefficient (n-	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	Under normal conditions of use, this material does not present a significant fire or explosion hazard.
Oxidizing properties	As a precautionary measure, keep away from strong oxidizers.

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:

Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

Incompatible Materials:

Strong oxidizers.

Hazardous Decomposition Products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological Information

Acute Toxicity

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

Product Data: No data available.

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Substance Data:

Name	Route	Result
Mineral oil	dermal	LD50 Rabbit: >2000 mg/kg
	oral	LD50 Rat: >5000 mg/kg
	inhalation	LC50 Rat: >5 mg/L (4 hr (aerosol))
Gentamicin sulfate	oral	LD50 Rat: >5000 mg/kg
Clotrimazole	oral	LD50 Rat: 708 mg/kg
Polyethylene	dermal	LD50 Rat: >2000 mg/kg
	oral	LD50 Rat: >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
Clotrimazole	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
Clotrimazole	Causes serious eye irritation.

Respiratory or Skin Sensitization

Assessment:

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

May cause an allergic skin reaction.

Product Data:

No data available.

Substance Data:

Name	Result
Gentamicin sulfate	May cause an allergic skin reaction.
	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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
Mineral oil	Group 3

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

OSHA Carcinogens: Not applicable

Germ Cell Mutagenicity

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

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Product Data:

No data available.

Substance Data: No data available.

Reproductive Toxicity**Assessment:**

May damage fertility or the unborn child.

Product Data:

No data available.

Substance Data:

Name	Result
Mometasone furoate	May damage fertility or 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
Mometasone furoate	Causes damage to organs.

Specific Target Organ Toxicity (Repeated Exposure)

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

Product Data:

No data available.

Substance Data:

Name	Result
Mometasone furoate	Causes damage to organs through prolonged or repeated exposure.

Aspiration toxicity**Assessment:**

May be fatal if swallowed and enters airways.

Product Data:

No data available.

Substance Data:

Name	Result
Mineral oil	May be fatal if swallowed and enters airways.

Information on Likely Routes of Exposure:

Skin and eye contact; oral ingestion.

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

See section 4 of this SDS.

Other Information:

No data available.

SECTION 12: Ecological Information

Acute (Short-Term) Toxicity

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

Product Data: No data available.

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Substance Data:

Name	Result
Mineral oil	Fish LC50 Oncorhynchus mykiss: >100 mg/L (96 hr [LL50])
	Aquatic Invertebrates LC50 Daphnia magna: >100 mg/L (48 hr [LL50])
Polyethylene	Fish LC50 Poecilia reticulata: > 100 mg/L (96 hr)
	Aquatic Invertebrates EC50 Daphnia magna: > 100 mg/L (48 hr [mobility])
	Aquatic Plants EC50 Desmodismus subspicatus: >100 mg/L (72 hr [growth rate, Read-across substance data])

Chronic (Long-Term) Toxicity

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

Product Data: No data available.

Substance Data:

Name	Result
Mineral oil	Aquatic Invertebrates EC50 Daphnia magna: >1000 mg/L (14 d [immobilization])
Polyethylene	Fish NOEC Salt water fish: 13,671.586 mg/L (28 d [mortality])
	Aquatic Invertebrates NOEC Daphnia magna: 17,475.27 mg/L (21 d [immobilisation, Read-across substance data])

Persistence and Degradability

Product Data: No data available.

Substance Data:

Name	Result
Mineral oil	The substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance
Polyethylene	The substance is readily biodegradable. 74.85% degradation in water, measured by O2 consumption, after 28 days.

Bioaccumulative Potential

Product Data: No data

available. **Substance Data:**

Name	Result
Mineral oil	The substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance
Polyethylene	The substance is not expected to bioaccumulate (log Pow=0.2 at 30 °C).

Mobility in Soil

Product Data: No data available.

Substance Data:

Name	Result
Mineral oil	The substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance
Polyethylene	The substance is mobile, therefore adsorption to soil is not expected (log Koc= 1.857 dimensionless at 25 °C).

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.

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Substance Data:

PBT assessment:

Polyethylene	The substance is not PBT.
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vPvB assessment:

Polyethylene	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 applicable regulatory entities

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

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SECTION 15: Regulatory Information

United States Regulations

Inventory Listing (TSCA):

8042-47-5	Mineral oil	Listed - Active
1405-41-0	Gentamicin sulfate	Not Listed
83919-23-7	Mometasone furoate	Not Listed
23593-75-1	Clotrimazole	Not Listed
25322-68-3	Polyethylene	Listed - Active

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:

8042-47-5	Mineral oil	Listed
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New Jersey Right to Know:

8042-47-5	Mineral oil	Listed
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New York Right to Know: None of the ingredients are listed.

Pennsylvania Right to Know:

8042-47-5	Mineral oil	Listed
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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