

SAFETY DATA SHEETS

This SDS packet was issued with item:

078937573

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

078937574 078937575 078937576

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial preparation date: 05.01.2016

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Revision date: 11.25.2020

Mozotic[™] (Gentamicin Sulfate, Ups; Mometasone Furoate Anhydrous, Usp; And Clotrimazole, Usp) Otic Suspension

SECTION 1: Identification

Product identifier

Product name: Mozotic[™] (Gentamicin Sulfate, Ups; Mometasone Furoate Anhydrous, Usp; And Clotrimazole, Usp) Otic Suspension

Product code: 21294610, 21294611, 21294612, 21294617

Recommended use of the product and restriction on use

Relevant identified uses: For Otic use in dogs only.

Uses advised against: Not for human use.

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:

Skin sensitization, category 1

Respiratory sensitization, category 1

Reproductive toxicity, category 1A

Label elements

Hazard pictograms:



Signal word: Danger

Hazard statements:

H317 May cause an allergic skin reaction

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

H360 May damage fertility or the unborn child

Precautionary statements:

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P201 Obtain special instructions before use
P202 Do not handle until all safety precautions have been read and understood
P261 Avoid breathing fume/mist/vapors
P272 Contaminated work clothing must not be allowed out of the workplace
P280 Wear protective gloves/protective clothing/eye protection/face protection
P284 Wear respiratory protection
P302+P352 IF ON SKIN: Wash with plenty of water
P333+P313 If skin irritation or rash occurs: Get medical advice/attention
P321 Specific treatment (see first aid instructions on this label)
P363 Wash contaminated clothing before reuse
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/doctor
P308+P313 IF exposed or concerned: Get medical advice/attention
P405 Store locked up
P501 Dispose of contents/container in accordance with all local, regional, state and federal regulations.

Hazards not otherwise classified: None

SECTION 3: Composition/information on ingredients

Identification	Name	Weight %
CAS number: 23593-75-1	Clotrimazole	1
CAS number: 1405-41-0	Gentamicin sulfate	0.3
CAS number: 83919-23-7	Mometasone furoate	0.1

Additional Information: None

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 symptoms develop or persist, seek medical advice/attention.

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:

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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:

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

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.

Delayed symptoms and effects:

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.

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

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.

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). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental precautions:

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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).

SECTION 8: Exposure controls/personal protection

Only those substances with limit values have been included below.

Occupational Exposure limit values:

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

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:

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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

Appearance	White to Off-white viscous suspension.
Odor	Oil odor
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	Miscible in water.
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.

Other information

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.

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Conditions to avoid:

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

Incompatible materials:

Strong oxidizing agents.

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.

Substance data:

Name	Route	Result
Clotrimazole	oral	LD50 Rat: 708 mg/kg
Gentamicin sulfate	oral	LD50 Rat: 5000 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 an allergic skin reaction.

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

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.

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Substance data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

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.

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: 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:

Inhalation, Ingestion, Skin contact, Eye contact.

Symptoms related to the physical, chemical and toxicological characteristics:

Refer to Section 4 of this SDS.

Other information:

No data available.

SECTION 12: Ecological information

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Acute (short-term) toxicity

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

Product data: No data available.

Substance data: No data available.

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: No data available.

Bioaccumulative potential

Product data: No data available.

Substance data:

Name	Result
Clotrimazole	Has the potential to bioaccumulate significantly (log Kow = 6.260).
Mometasone furoate	Has the potential to bioaccumulate (log Kow = 3.9 to 4.115).

Mobility in soil

Product data: No data available.

Substance data: No data available.

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: 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.

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

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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 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:

23593-75-1	Clotrimazole	Not Listed
1405-41-0	Gentamicin sulfate	Not Listed
83919-23-7	Mometasone furoate	Not Listed

New Jersey Right to Know:

23593-75-1	Clotrimazole	Not Listed
1405-41-0	Gentamicin sulfate	Not Listed
83919-23-7	Mometasone furoate	Not Listed

New York Right to Know:

23593-75-1	Clotrimazole	Not Listed
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1405-41-0	Gentamicin sulfate	Not Listed
83919-23-7	Mometasone furoate	Not Listed

Pennsylvania Right to Know:

23593-75-1	Clotrimazole	Not Listed
1405-41-0	Gentamicin sulfate	Not Listed
83919-23-7	Mometasone furoate	Not Listed

California Proposition 65: None of the ingredients are listed.

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.

NFPA: 2-0-0

HMIS: 2*-0-0

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Revision Notes:

Revision Date	Notes
2020-11-25	Version 2.

End of Safety Data Sheet