Printing date 01/08/2024 Reviewed on 01/08/2024

Safety Data Sheet

acc. to OSHA HCS

1 Identification

· Product identifier

· Trade name: Mometasone Furoate
Mometasoni furoas

· Article number: 701834, 104324

• CAS Number: 83919-23-7 • EC number:

617-501-0

· Application of the substance / the mixture Pharma Active ingredients

· Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Fagron Inc 2400 Pilot Knob Road St. Paul, MN 55120 www.fagron.us QA@fagron.us

· Information department:

Tel.: 800-423-6967 Fax: 800-339-1596

Emergency telephone number:

Emergency Telephone: US: 1-800-535-5053

International: 1-352-323-3500

2 Hazard(s) identification

· Classification of the substance or mixture

Toxic to Reproduction 2

H361 Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity - Repeated ExposureH372 Causes damage to organs through prolonged or repeated exposure.

- · Label elements
- · GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



- · Signal word Danger
- · Hazard statements

Suspected of damaging fertility or the unborn child.

Causes damage to organs through prolonged or repeated exposure.

· Precautionary statements

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.

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Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Wear protective gloves/protective clothing/eye protection/face protection.

IF exposed or concerned: Get medical advice/attention.

Get medical advice/attention if you feel unwell.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- Classification system:
- · NFPA ratings (scale 0 4)



Health = 1 Fire = 0 Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 1 Fire = 0

REACTIVITY 0 Reactivity = 0

- · Other hazards
- · Results of PBT and vPvB assessment
- PBT: Not applicable.vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Substances

· CAS No. Description

CAS: 83919-23-7 Mometasone Furoate

Mometasoni furoas

- · Identification number(s)
- EC number: 617-501-0

4 First-aid measures

- · Description of first aid measures
- General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: If skin irritation continues, consult a doctor.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: Rinse out mouth and then drink plenty of water.
- Information for doctor:
- \cdot Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed No further relevant information available.

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5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

Carbon dioxide

Fire-extinguishing powder

Foam

Water spray

Use fire fighting measures that suit the environment.

· Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Hydrogen chloride (HCI)

- · Advice for firefighters
- · Protective equipment:

Wear fully protective suit.

Wear self-contained respiratory protective device.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Ensure adequate ventilation
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to section 13.

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

- · Protective Action Criteria for Chemicals
- · PAC-1: Substance is not listed.
- · PAC-2: Substance is not listed.
- · PAC-3: Substance is not listed.

7 Handling and storage

- · Handling:
- · Precautions for safe handling No special precautions are necessary if used correctly.
- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see section 7.

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- · Control parameters
- · Components with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

Nitrile rubber, NBR

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- General Information
- · Appearance:

Form: Powder
Color: Whitish

Odor: Recognizable
Odor threshold: Not determined.

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pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	218-220°C (424.4-428°F)
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Product is not flammable.
Decomposition temperature:	Not determined.
Ignition temperature:	Not determined.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not applicable.
Density:	Not determined.
Relative density	Not determined.
Vapor density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Insoluble.
Partition coefficient (n-octanol/	water): Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Other information	No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions Reacts with strong oxidizing agents.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: Chlorine compounds

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11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

Oral LD50 >2000 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer) Substance is not listed.
- · NTP (National Toxicology Program) Substance is not listed.
- · OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

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14 Transport information

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· UN-Number		
· DOT, IMDG, IATA	not regulated	
· UN proper shipping name		
· DOT, IMDG, IATA	not regulated	
· Transport hazard class(es)		
DOT ADN IMDG IATA		

· DOT, ADN, IMDG, IATA

· Class not regulated

· Packing group

· DOT, IMDG, IATA not regulated

• Environmental hazards: Not applicable.

· Special precautions for user Not applicable.

 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

· UN "Model Regulation": not regulated

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · Sara
- · Section 355 (extremely hazardous substances): Substance is not listed.
- · Section 313 (Specific toxic chemical listings): Substance is not listed.
- · TSCA (Toxic Substances Control Act): Substance is not listed.
- · Hazardous Air Pollutants Substance is not listed.
- · Proposition 65
- · Chemicals known to cause cancer: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for females: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for males: Substance is not listed.
- Chemicals known to cause developmental toxicity: Substance is not listed.
- · Carcinogenic categories
- · EPA (Environmental Protection Agency) Substance is not listed.
- TLV (Threshold Limit Value) Substance is not listed.
- · NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing SDS:

Fagron US

Quality Assurance

· Contact: QA@fagron.us



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· Date of preparation / last revision 01/08/2024

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Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

Toxic to Reproduction 2: Reproductive toxicity - Category 2

Specific Target Organ Toxicity - Repeated Exposure 1: Specific target organ toxicity (repeated exposure) - Category 1

* Data compared to the previous version altered.

USA

