


## SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Mometasone Furoate  
Mometasoni furoas
- **Article number:** 701834, 104324
- **CAS Number:**  
83919-23-7
- **EC number:**  
617-501-0
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Pharma Active ingredients
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
FAGRON a.s.  
Holická 1098/31m  
779 00 Olomouc  
Česká republika
- **Further information obtainable from:**  
Tel.: +420 585 222 590  
info@fagron.cz
- **1.4 Emergency telephone number:**  
Toxikologické informační středisko,  
Na Bojišti 1,  
128 08 Praha 2  
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),  
e-mail:tis.cuni@cesnet.cz

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Repr. 2 H361 Suspected of damaging fertility or the unborn child.  
STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**  
  
GHS08
- **Signal word** Danger
- **Hazard statements**  
H361 Suspected of damaging fertility or the unborn child.  
H372 Causes damage to organs through prolonged or repeated exposure.

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• **Precautionary statements**

- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P264 Wash thoroughly after handling.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

• **2.3 Other hazards**

• **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

\* **SECTION 3: Composition/information on ingredients**

• **3.1 Substances**

• **CAS No. Description**

CAS: 83919-23-7 Mometasone Furoate  
Mometasoni furoas

• **Identification number(s)**

- **EC number:** 617-501-0

\* **SECTION 4: First aid measures**

• **4.1 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.

• **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

• **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

\* **SECTION 5: Firefighting measures**

• **5.1 Extinguishing media**

• **Suitable extinguishing agents:**

Carbon dioxide  
Fire-extinguishing powder  
Foam  
Water spray  
Use fire extinguishing methods suitable to surrounding conditions.

• **5.2 Special hazards arising from the substance or mixture**

In case of fire, the following can be released:

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Hydrogen chloride (HCl)

- **5.3 Advice for firefighters**
- **Protective equipment:**  
Wear fully protective suit.  
Wear self-contained respiratory protective device.

## **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Ensure adequate ventilation
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to section 13.
- **6.4 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.

## **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

## **SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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· **Hand protection**



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/face protection**



Tightly sealed goggles

· **Body protection:** Protective work clothing

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Solid

· **Colour:**

Whitish

· **Odour:**

Recognisable

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

218–220°C

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Product is not flammable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **pH**

Not applicable.

· **Viscosity:**

· **Kinematic viscosity**

Not applicable.

· **Dynamic:**

Not applicable.

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- **Solubility**
- **water:** Insoluble.
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not applicable.
- **Density and/or relative density**
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Particle characteristics**  
See section 3.

- **9.2 Other information**
- **Appearance:**
- **Form:** Powder
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Not determined.
- **Explosive properties:** Product does not present an explosion hazard.
- **Change in condition**
- **Evaporation rate** Not applicable.

- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

\* **SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.

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- **10.3 Possibility of hazardous reactions** Reacts with strong oxidising agents.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Chlorine compounds

## **SECTION 11: Toxicological information**

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

### **LD/LC50 values relevant for classification:**

Oral	LD50	>2000 mg/kg (rat)
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- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Suspected of damaging fertility or the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Causes damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

## **SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (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.

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Recommendation

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

#### European waste catalogue

HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP10	Toxic for reproduction

#### Uncleaned packaging:

**Recommendation:** Disposal must be made according to official regulations.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADR, IMDG, IATA not regulated

### 14.2 UN proper shipping name

ADR, IMDG, IATA not regulated

### 14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class not regulated

### 14.4 Packing group

ADR, IMDG, IATA not regulated

### 14.5 Environmental hazards:

Not applicable.

### 14.6 Special precautions for user

Not applicable.

### 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

### UN "Model Regulation":

not regulated

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

#### Directive 2012/18/EU

**Named dangerous substances - ANNEX I** Substance is not listed.

#### DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

Substance is not listed.

#### REGULATION (EU) 2019/1148

**Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

Substance is not listed.

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- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS** Substance is not listed.
- **Regulation (EC) No 273/2004 on drug precursors** Substance is not listed.
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors** Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## **SECTION 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 Česká republika
- **Contact:** msds@fagron.cz
- **Date of previous version:** 05.01.2024
- **Version number of previous version:** 2.2

- **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

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Repr. 2: Reproductive toxicity – Category 2

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

- **\* Data compared to the previous version altered.**

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