

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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Revision: XX/XX/XXXX

Version: 00



## MOMETASONI FUROAS

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name:	Mometasone furoate Mometasoni furoas Mometasonfuroaat Mométasone (furoate de) Mometasonfuroat
N° CAS:	83919-23-7
N° EC:	617-501-0

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Repr. 2	H361
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#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s):  
Attention  
Warning

Hazard statements:

H361 Suspected of damaging fertility or the unborn child.

Precautionary statements:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

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P281 Use personal protective equipment as required.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
P405 Store locked up.  
P501 Dispose of contents/container at hazardous or special waste collection point.  
Dispose in a safe manner in accordance with the local/national regulations.

Additional applicable label elements:



### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name: Mometasone furoate  
IUPAC name: (11beta,16alpha)-9,21-Dichloro-17-[(2-furanylcarbonyl)oxy]-11-hydroxy-16-methylpregna-1,4-diene-3,20-dione  
Synonyms: Nasonex  
SCH 32088  
Asmanex  
N° CAS: 83919-23-7  
N° EC: 617-501-0  
Molecular Formula:  $C_{27}H_{30}Cl_2O_6$   
Content: 98.0 per cent to 102.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes: Consult a physician. Show this safety data sheet to the doctor in attendance.  
After inhalation: Assure fresh air breathing. If you feel unwell, seek medical advice.  
After skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.  
After eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persists.  
After ingestion: Rinse mouth. If swallowed, seek medical advice immediately and show this container or label.

### 4.2 Most important symptoms and effects, both acute and delayed

Not available.

### 4.3 Indication of any immediate medical attention and special treatment needed

Not available.

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### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media: Water spray, carbon dioxide and dry powder.  
Surrounding fires: Use water spray or fog for cooling exposed containers.

Unsuitable extinguishing media: Do not use a heavy water stream.

#### 5.2 Special hazards arising from the substance/mixture

Not available.

#### 5.3 Advice for firefighters

Surrounding fires: Not available.  
Protection against fire: Do not enter fire area without proper protective equipment, including respiratory protection.  
Hazardous combustion products: Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

##### For non-emergency personnel

Remove ignition sources. Evacuate area. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

##### For emergency responders

Remove ignition sources. Evacuate area.

#### 6.2 Environmental precautions

Not available.

#### 6.3 Methods and material for containment and cleaning up

Clean spills promptly. To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution. Ensure adequate ventilation.

#### 6.4 Reference to other sections

Not available.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling: Normal measures for preventive fire protection.  
Personal protection: Not available.  
Technical protective measures: Provide appropriate exhaust ventilation at places where dust is formed.  
Handling: Not available.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

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Conditions for safe storage, including any incompatibilities:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: Store between 15°C to 30 °C.

Storage – away from:

Not available.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Provide local exhaust or general room ventilation. Material should be handled in a laboratory hood whenever possible.

#### Individual protection measures

Eye/face protection: Chemical goggles or safety glasses.

Skin protection: Wear suitable protective clothing.

Hand protection: Wear suitable gloves resistant to chemical penetration.

Respiratory protection: Wear approved mask (P2). In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards: Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: White or almost white powder.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: About 220 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

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Relative density:	Not available.
Solubility:	Soluble in acetone and in methylene chloride, slightly soluble in ethanol (96 %).
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Stable under normal conditions.

### 10.2 Chemical stability

Stable under normal conditions.

Hazardous polymerization: Will not occur.

### 10.3 Possibility of hazardous reactions

None under normal conditions.

### 10.4 Conditions to avoid

None known.

### 10.5 Incompatible materials

Strong oxidisers.

### 10.6 Hazardous decomposition products

Carbon dioxide. Chlorides. Carbon monoxide. When heated to decomposition, emits dangerous fumes.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD <sub>50</sub> (rat): > 3000 mg/kg Causes depression of the respiratory system. Dry nose.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.

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Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	RTECS: TU3822000

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Product: Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with the local/national regulations.  
Contaminated packaging: Dispose of as unused product.

## SECTION 14: TRANSPORT INFORMATION

### Transport information according to ADR/RID/IMDG/ICAO/IATA

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

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### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.6 Special precautions for user

Not available.

### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

### 14.8 Additional transport information

Not available.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Harmful

Risk phrases:

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

Safety phrases:

S1 Keep locked up.

S22 Do not breathe dust.

S36/37 Wear suitable protective clothing and gloves.

S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label when possible).

S53 Avoid exposure – obtain special instructions before use.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

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## MOMETASONI FUROAS

### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.  
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department  
FAC SECUNDUM ARTEM NV  
[info@magis-pharma.be](mailto:info@magis-pharma.be)



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