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

· 1.1 Product identifier

 Trade name: <u>Mometasone Furoate</u> 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 UK Ltd 4B Coquet St Newcastle upon Tyne England NE1 2QB Tel. 0845 6522525

• Further information obtainable from: Emergency response telephone number: +44 (0) 845 652 2525

• **1.4 Emergency telephone number:** Emergency response telephone number: +44 (0) 845 652 2525

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 GB CLP regulation.

Hazard pictograms



· Signal word Danger

· Hazard statements

H361 Suspected of damaging fertility or the unborn child.

H372 Causes damage to organs through prolonged or repeated exposure.

· Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.



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· Dooulto of	DPT and vDvP accomment
· 2.3 Other h	hazards
	regulations.
P501	Dispose of contents/container in accordance with local/regional/national/international
P405	Store locked up.
P308+P313	3 IF exposed or concerned: Get medical advice/attention.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
F 204	Wash thoroughly after handling.

Results of PBT and vPvB assessment

Wash thoroughly after handling

• **PBT:** Not applicable.

DOGA

· 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: Hydrogen chloride (HCl)

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· 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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(Contd. of page 3) · 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. · Viscositv: 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.
· 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
Organic peroxides	
· Corrosive to metals	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.
- 10.3 Possibility of hazardous reactions Reacts with strong oxidising agents.
- 10.4 Conditions to avoid No further relevant information available.



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• **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)

• Reproductive toxicity Suspected of damaging fertility or the unborn child.

- · STOT-repeated exposure Causes damage to organs through prolonged or repeated exposure.
- · 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.

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.

· Uncleaned packaging:

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

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SECTION 14: Transport info	ormation	
 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 accordi IMO instruments 	ing to 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.
- · 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 UK

Quality Assurance

- · Contact: quality@fagron.co.uk
- · 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

- IMDG: International Maritime Code for Dangerous Good 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.

