

# Material Safety Data Sheet

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

## MEBEVERINI HYDROCHLORIDUM

EN

FORM-06-14-01 (V00)

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

#### 1.1 Product identifier

Product name:	Mebeverine hydrochloride Mebeverini hydrochloridum Mebeverine hydrochloride Mébévérine (chlorhydrate de) Mebeverin Hydrochlorid
N° CAS:	2753-45-9
N° EC:	220-400-0

#### 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

Acute Tox. 4	H302
Eye Dam. 1	H318
Aquatic Chronic 1	H410

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H302 Harmful if swallowed.

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H318	Causes serious eye damage.
H410	Very toxic to aquatic life with long-lasting effects.
Precautionary statements:	
P260	Do not breathe dust/fumes/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P314	Get medical advice/attention if you feel unwell.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.
Additional applicable label elements:	Not applicable.

### 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

Product name:	Mebeverine hydrochloride
IUPAC name:	4-[ethyl-[1-(4-methoxyphenyl)propan-2-yl]amino]butyl 3,4-dimethoxybenzoate;hydrochloride
Synonyms:	Duspatalin Colofac
N° CAS:	2753-45-9
N° EC:	220-400-0
Molecular Formula:	C <sub>25</sub> H <sub>36</sub> ClNO <sub>5</sub>
Content:	99.0 per cent to 101.0 per cent (dried substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Symptoms of poisoning may occur even after several hours; therefore, medical observation for at least 48 hours after the accident is recommended.
After inhalation:	Supply fresh air; consult doctor in case of complaints.
After skin contact:	Immediately wash with water and soap and rinse thoroughly.
After eye contact:	Rinse opened eye for several minutes under running water.
After ingestion:	Rinse mouth. Do not induce vomiting. Seek medical treatment.

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

Not available.

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

Not available.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: Use fire extinguishing methods suitable for surrounding conditions.

Unsuitable extinguishing media: Not available.

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

Formation of toxic gases is possible during heating or in case of fire.

### 5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self-contained respiratory protective device.

Hazardous combustion products: Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

#### For non-emergency personnel

Wear protective clothing.

#### For emergency responders

Wear protective clothing.

### 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 of 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

Precautions for safe handling: Store in cool, dry place in tightly closed receptacles.

Information about fire - and explosion protection: No special measures required.

Personal protection: Not available.

Technical protective measures: Not available.

Handling: Not available.

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

Storage:	Store only in the original receptacle unless other advice is given.
Conditions for safe storage, including any incompatibilities:	Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Keep container in a well-ventilated place.
Storage – away from:	Keep away from sources of ignition and heat. Protected from light. Store away from foodstuffs.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace: Not required.

### 8.2 Exposure controls

#### Appropriate engineering control

Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Store protective clothing separately.

#### Individual protection measures

Eye/face protection: Tightly sealed goggles.

Skin protection: Not determined.

Hand protection: Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374

Material of gloves: Butyl rubber, BR.

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.

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.

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, crystalline powder.

Odour: Odourless.

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Odour threshold:	Not determined.
pH:	Not applicable.
Melting/freezing point:	131 °C
Initial boiling point:	Not determined.
Boiling range:	Not determined.
Flash point:	Not applicable.
Evaporation rate:	Not applicable.
Flammability (solid/gas):	Not determined.
Upper/lower flammability or explosive limits:	Not determined.
Vapour pressure:	Not applicable.
Vapour density:	Not determined.
Relative density:	Not determined.
Solubility:	Very soluble in methylene chloride, freely soluble in ethanol (96 per cent).
Solubility in water:	Very soluble in water.
Partition coefficient (n-octanol/water):	Not determined.
Auto-ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
Viscosity:	Not applicable.
Explosive properties:	Not determined.
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.

Thermal decomposition/conditions to be avoided: Formation of toxic gases is possible during heating or in case of fire.

### 10.3 Possibility of hazardous reactions

No dangerous reactions known.

### 10.4 Conditions to avoid

Heat.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

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Formation of toxic gases is possible during heating or in case of fire.

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Harmful if swallowed. Oral LD <sub>50</sub> (rat): 1 540 mg/kg
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Causes serious eye damage.
Respiratory/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:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Based on available data, the classification criteria are not met.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	May cause damage to organs through prolonged or repeated exposure.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	RTECS: YX5425000

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

Eye contact:	Causes serious eye damage.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed.
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.

#### Additional ecological information:

General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product to reach ground water, water course or sewage system.

#### 12.5 Results of PBT and vPvB assessment

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PBT: Not applicable. vPvB: Not applicable.

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

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

European waste catalogue: Waste disposal key numbers from EWC have to be assigned depending on origin and processing.

Contaminated packaging: Recommendation: Dispose of in accordance with national regulations. Recommended cleansing agents: Water, if necessary together with cleansing agents.

## 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.

#### 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 applicable.

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

Not applicable.

#### 14.8 Additional transport information

Not available.

## SECTION 15: REGULATORY INFORMATION

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

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Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.

R41 Risk of serious damage to eyes.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

S20/21 When using do not eat, drink or smoke.

S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

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

### 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.

### 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



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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

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