

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

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Mebeverine hydrochloride
Chemical name	: Mebeverine hydrochloride
EC-No.	: 220-400-0
CAS-No.	: 2753-45-9
Product code	: 201700612

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

##### Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

##### Uses advised against

Restrictions on use	: Not for food, drug or home use
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#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
7, Allée Kastner, CS30026  
F 67081 Strasbourg  
France  
T +33(0)388412035, F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu), [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4	H302
Serious eye damage/eye irritation, Category 1	H318
Hazardous to the aquatic environment – Acute Hazard, Category 1	H400
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410

Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Very toxic to aquatic life with long lasting effects. Causes serious eye damage.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

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- Hazard statements (CLP) : H302 - Harmful if swallowed.  
H318 - Causes serious eye damage.  
H410 - Very toxic to aquatic life with long lasting effects.
- Precautionary statements (CLP) : P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P273 - Avoid release to the environment.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P310 - Immediately call a POISON CENTER or doctor.  
P330 - Rinse mouth.  
P391 - Collect spillage.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP) :



GHS05

### 2.3. Other hazards

- Other information : Active substance (in pharmaceutical products).  
Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Mebeverine hydrochloride	CAS-No.: 2753-45-9 EC-No.: 220-400-0	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=1540 mg/kg bodyweight) Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H- and EUH-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Consult an eye specialist immediately.
- First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

- Symptoms/effects after eye contact : Causes serious eye damage. Redness, pain.

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
- Unsuitable extinguishing media : Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

### 5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

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

- General measures : Avoid contact with skin, eyes and clothing.

#### For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

#### For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

- For containment : Absorb with an inert material and place in an appropriate waste disposal container.
- Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

### 6.4. Reference to other sections

See Section 13 for disposal information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
- Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

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

- Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
- Packaging materials : Keep in original containers.

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### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### Personal protection equipment

##### Eye and face protection

##### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

##### Skin protection

##### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

##### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

##### Respiratory protection

##### Respiratory protection:

In case of dust formation use respirator with filter: P3

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white, almost white.
Appearance	: Crystalline powder.
Molecular mass	: 466.01 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 105 – 130 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 4.5 – 6.5
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable

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Particle size : Not available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

No additional information available

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Harmful if swallowed.  
Acute toxicity (dermal) : Not classified (Lack of data)  
Acute toxicity (inhalation) : Not classified (Lack of data)

#### Mebeverine hydrochloride (2753-45-9)

LD50 oral rat	1540 mg/kg (RTECS No YX5425000)
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Skin corrosion/irritation	: Not classified (Lack of data) pH: 4.5 – 6.5
Serious eye damage/irritation	: Causes serious eye damage. pH: 4.5 – 6.5
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Lack of data)

### 11.2. Information on other hazards

No additional information available

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Very toxic to aquatic life.

Hazardous to the aquatic environment, long-term (chronic) : Very toxic to aquatic life with long lasting effects.

Mebeverine hydrochloride (2753-45-9)	
LC50 - Fish [1]	10.2 mg/l (96 Hours, Brachydanio rerio (zebra-fish))
EC50 - Crustacea [1]	14 mg/l (48 Hours, Daphnia magna (Water flea))
ErC50 algae	0.87 mg/l (72 Hours, Selenastrum capricornutum)

#### 12.2. Persistence and degradability

Mebeverine hydrochloride (2753-45-9)	
Persistence and degradability	Rapidly degradable

#### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Endocrine disrupting properties

No additional information available

#### 12.7. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

No additional information available

### SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>		
Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>		
Not applicable	Not applicable	Not applicable

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ADR	IMDG	IATA
<b>14.4. Packing group</b>		
Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>		
Not applicable	Not applicable	Not applicable
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

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

Not applicable

## SECTION 15: Regulatory information

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

#### EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.2. Chemical safety assessment

No additional information available

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### SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	<b>Added</b>
	Revision date	<b>Added</b>
1.1	EC-No.	<b>Added</b>
1.1	CAS-No.	<b>Added</b>
1.1	Name	<b>Modified</b>
1.2	Main use category	<b>Removed</b>
1.2	Restrictions on use	<b>Modified</b>
1.2	Use of the substance/mixture	<b>Modified</b>
2.1	Adverse physicochemical, human health and environmental effects	<b>Modified</b>
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<b>Modified</b>
2.2	Hazard pictograms (CLP)	<b>Modified</b>
2.2	Precautionary statements (CLP)	<b>Modified</b>
2.2	Hazard statements (CLP)	<b>Modified</b>
2.2	Signal word (CLP)	<b>Modified</b>
2.3	Other information	<b>Added</b>
4.1	First-aid measures after skin contact	<b>Modified</b>
4.1	First-aid measures after eye contact	<b>Modified</b>
4.1	First-aid measures general	<b>Added</b>
4.1	First-aid measures after ingestion	<b>Added</b>
4.1	First-aid measures after inhalation	<b>Added</b>
4.2	Symptoms/effects after eye contact	<b>Added</b>
5.1	Unsuitable extinguishing media	<b>Added</b>
5.1	Suitable extinguishing media	<b>Modified</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.2	Fire hazard	<b>Removed</b>
5.3	Protection during firefighting	<b>Added</b>
5.3	Firefighting instructions	<b>Modified</b>
6.1	Protective equipment	<b>Added</b>
6.1	General measures	<b>Added</b>
6.1	Emergency procedures	<b>Modified</b>
6.2	Environmental precautions	<b>Added</b>
6.3	Methods for cleaning up	<b>Added</b>
6.3	For containment	<b>Added</b>
6.4	Reference to other sections (8, 13)	<b>Added</b>



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Indication of changes		
Section	Changed item	Comments
7.1	Precautions for safe handling	<b>Added</b>
7.1	Hygiene measures	<b>Added</b>
7.2	Storage conditions	<b>Added</b>
7.2	Packaging materials	<b>Added</b>
7.3	Specific end uses	<b>Removed</b>
8.2	Hand protection	<b>Modified</b>
8.2	Skin and body protection	<b>Modified</b>
8.2	Respiratory protection	<b>Added</b>
8.2	Eye protection	<b>Added</b>
8.2	Appropriate engineering controls	<b>Modified</b>
9	Colour	<b>Added</b>
9	Melting point	<b>Added</b>
9	pH	<b>Added</b>
9	Molecular mass	<b>Added</b>
9	Solubility in water	<b>Removed</b>
10.1	Reactivity	<b>Removed</b>
10.3	Possibility of hazardous reactions	<b>Removed</b>
10.5	Incompatible materials	<b>Removed</b>
10.6	Hazardous decomposition products	<b>Removed</b>
11.1	LD50 oral rat	<b>Modified</b>
11.1	ATE CLP (oral)	<b>Modified</b>
12.1	LC50 - Fish [1]	<b>Added</b>
12.1	EC50 - Crustacea [1]	<b>Added</b>
12.1	Ecology - general	<b>Removed</b>
12.1	ErC50 algae	<b>Added</b>

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Safety Data Sheet (SDS), EU

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