

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Substance
Trade name	: MEBEVERINE HYDROCHLORIDE
Chemical name	: 4-[Ethyl (4-methoxy-alpha-mthylphenethyl) amino] butylvertrate hydrochloride
IUPAC name	: 4-[Ethyl-[1-(4-methoxyphenyl)propan-2-yl]amino]butyl 3,4-dimethoxybenzoate hydrochloride
EC-No.	: 220-400-0
CAS-No.	: 2753-45-9
Product code	: 91470
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C ₂₅ H ₃₅ NO ₅ .HCl
Synonyms	: 4-[Ethyl (4-methoxy-alpha-mthylphenethyl) amino] butylvertrate hydrochloride
Other means of identification	: SMILES: O=C(C(C=C1OC)=CC=C1OC)OCCCCN(CC)C(C)CC(C=C2)=CC=C2OC

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category	: API, Medicinal use, Professional use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only
Use of the substance/mixture	: Antispasmodic
Function or use category	: Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet**Head office**

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Manufacturer

BENECHIM S.R.L.
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Belgium
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1.4. Emergency telephone number

Emergency number	: +34 93 586 05 20 / +32 (0) 70 245 245 (9:00 - 17:00)
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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
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412
Full text of H- and EUH-statements: see section 16	

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Adverse physicochemical, human health and environmental effects

Dust may form explosive mixture in air. Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed.

H412 - Harmful 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.

P301+P312 - IF SWALLOWED: Call a POISON CENTER, doctor if you feel unwell.

P330 - Rinse mouth.

P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Other hazards which do not result in classification : May ignite spontaneously if exposed to air.

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type

: Mono-constituent

Name	Product identifier	%
MEBEVERINE HYDROCHLORIDE	CAS-No.: 2753-45-9 EC-No.: 220-400-0	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation

: Allow affected person to breathe fresh air. Allow the victim to rest.

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. Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.

First-aid measures after eye contact

: Rinse immediately with plenty of water. If eye irritation persists: Get medical advice/attention. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion

: Rinse mouth. Immediately call a POISON CENTER/doctor. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects after ingestion

: Swallowing a small quantity of this material will result in serious health hazard.

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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray. Foam. Dry powder. Carbon dioxide. Sand. Do not use a solid water stream as it may scatter and spread fire.
- Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire. Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : In case of fire and/or explosion do not breathe fumes.
- Explosion hazard : Avoid raising powdered material due to explosion hazard.
- Hazardous decomposition products in case of fire : fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides.

5.3. Advice for firefighters

- Precautionary measures fire : Keep away from combustible materials. Minimize generation of dust which may be combustible.
- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Remove ignition sources. Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Use personal protective equipment as required. Dust/aerosol mask. Safety glasses. Protective gloves. Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Avoid dust formation. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Do not handle until all safety precautions have been read and understood.

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Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at room temperature. Keep only in the original container in a cool, well ventilated place away from : Oxidizing agent, Heat sources, Direct sunlight. Keep container closed when not in use.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage area : Store in a well-ventilated place.

7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 2 (0.1 - 1 mg/m³)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Local exhaust or breathing protection. Ensure good ventilation of the work station. Do not breathe dust. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Dust/aerosol mask with filter type P3. Gloves. Protective goggles. Protective clothing. Avoid all unnecessary exposure.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

Eye protection		
Type	Field of application	Standard
Safety glasses	Dust, Fine dust	EN 166

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8.2.2.2. Skin protection

Skin and body protection:

Long sleeved protective clothing

Skin and body protection	
Type	Standard
Disposable gowns, Reusable gowns, Tyvek® Gown/Coveralls	EN 13034, EN 1149-1

Hand protection:

In case of repeated or prolonged contact wear gloves. Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Natural rubber, Butyl rubber, Polyvinylchloride (PVC), Latex, Neoprene rubber (HNBR), Fluoroelastomer (FKM)	EN 374-2

Other skin protection Materials for protective clothing		
Condition	Material	Standard
Good resistance:	Synthetic material, Tyvek®, Polyethylene	EN 13034, EN ISO 13982-1

8.2.2.3. Respiratory protection

Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask, Full face mask, Powered mask	P3	High dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Molecular mass	: 466.1 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 135 °C
Freezing point	: Not available
Boiling point	: 543.8
Flammability	: Non flammable.
Explosive properties	: May form combustible dust concentrations in air.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable

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Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Soluble in water.
Partition coefficient n-octanol/water (Log Kow)	: 4.87 (Mebeverine free base, calculated using ALOGPs)
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
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Dust Cloud minimum Flammability Temperature	: 320 °C
Layer Minimum flammability Temperature	: > 400 °C
Explosivity Pmax	: 8.5 bar
Explosion Severity Factor Kmax (bar.m/s)	: : 208
Explosion Class	: St2

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7. Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide. Nitrogen oxides. fume.

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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
Acute toxicity (inhalation)	: Not classified

MEBEVERINE HYDROCHLORIDE (2753-45-9)	
LD50 oral rat	1540 mg/kg
LD50 dermal rat	> 2000 mg/kg
LD50, intraperitoneal, mouse	150 mg/kg
LD50, intravenous, rat	17.7 mg/kg

Skin corrosion/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605
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11.2.2. Other information

Potential adverse human health effects and symptoms	: Harmful if swallowed.
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SECTION 12: Ecological information

12.1. Toxicity

Ecology - water	: Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Harmful to aquatic life with long lasting effects.

MEBEVERINE HYDROCHLORIDE (2753-45-9)	
LC50, 96 h, Minnow	mg/l
EC50, 48H	14 mg/l

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12.2. Persistence and degradability

MEBEVERINE HYDROCHLORIDE (2753-45-9)

Persistence and degradability	Minimally biodegradable. May cause long-term adverse effects in the environment.
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12.3. Bioaccumulative potential

MEBEVERINE HYDROCHLORIDE (2753-45-9)

Partition coefficient n-octanol/water (Log Kow)	4.87 (Mebeverine free base, calculated using ALOGPs)
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Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

MEBEVERINE HYDROCHLORIDE (2753-45-9)

vPvB: not relevant – no registration required

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.
Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with / ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

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14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail 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

15.1.1. 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)

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REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

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

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)

15.1.2. National regulations

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen –

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Switzerland

Storage class (LK) : LK 11/13 - Solids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
H302	Harmful if swallowed.
H412	Harmful to aquatic life with long lasting effects.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.