

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

Product form	: Substance
Trade name	: TRIMEBUTINE MALEATE
Chemical name	: 3,4,5-TRIMETHOXYBENZOIC ACID 2-(DIMETHYLAMINO)-2-PHENYLBUTYL ESTER MALEATE SALT
IUPAC name	: (Z)-but-2-enedioic acid;[2-(dimethylamino)-2-phenylbutyl] 3,4,5-trimethoxybenzoate
EC-No.	: 251-845-9
CAS-No.	: 34140-59-5
Product code	: 78510
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C22H29NO5 . C4H4O4
Synonyms	: (1-Ethyl-1-phenyl-2-(3,4,5-trimethoxybenzoyloxy)ethyl)dimethylammonium hydrogen maleate; 3,4,5-trimethoxy-benzoic acid beta-(dimethylamino)-beta-ethylphenethyl ester; Trimebutine Maleate
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: SMILES: CCC(COC(=O)c1cc(c(c(c1)OC)OC)OC)(c2ccccc2)N(C)C(=C\C(=O)O)\C(=O)O

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

Main use category	: API,Industrial use,Medicinal use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use For professional use only Industrial
Use of the substance/mixture	: Gastrointestinal tract regulator
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**

MOEHS IBÉRICA, S.L.  
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**1.4. Emergency telephone number**

Emergency number	: +34 93 586 05 20 (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]**

Not classified

# TRIMEBUTINE MALEATE

## Safety Data Sheet

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

### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice. Dust may form explosive mixture in air.

### 2.2. Label elements

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

No labelling applicable

### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
TRIMEBUTINE MALEATE	CAS-No.: 34140-59-5 EC-No.: 251-845-9	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.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

### 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	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
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 : Nitrogen oxides. Carbon monoxide. Carbon dioxide.

### 5.3. Advice for firefighters

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.

# TRIMEBUTINE MALEATE

## Safety Data Sheet

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

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

##### 6.1.1. For non-emergency personnel

Emergency procedures : Avoid breathing dust. Evacuate unnecessary personnel.

##### 6.1.2. For emergency responders

Protective equipment : Use personal protective equipment as required. Equip cleanup crew with proper protection.  
Emergency procedures : Ventilate area.

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

#### 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

See Section 8. Exposure controls and personal protection.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.  
Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not get in eyes, on skin, or on clothing. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Eliminate all ignition sources if safe to do so. Avoid dust formation.  
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

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

Technical measures : Provide local exhaust or general room ventilation.  
Storage conditions : Store at room temperature. Keep only in the original container in a cool, well ventilated place away from : Heat sources, Direct sunlight. Keep container closed when not in use.  
Incompatible products : Strong bases. Strong acids. Oxidizing agent.  
Incompatible materials : Sources of ignition. Direct sunlight.

#### 7.3. Specific end use(s)

No additional information available

### 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

# TRIMEBUTINE MALEATE

## Safety Data Sheet

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

### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 1 (> 1 mg/m<sup>3</sup>)

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

No additional information available

### 8.2.2. Personal protection equipment

#### Personal protective equipment:

Safety glasses. Gloves. Dust/aerosol mask with filter type P3.

#### 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	EN 166

#### 8.2.2.2. Skin protection

##### Hand protection:

Wear protective gloves.

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

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type 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.

# TRIMEBUTINE MALEATE

## Safety Data Sheet

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

### SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: white.
Appearance	: Dust.
Molecular mass	: 503.54 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 129 – 133 °C (According ACD/LABS)
Freezing point	: Not available
Boiling point	: 458 °C 760 mmHg (According ACD/LABS)
Flammability	: Non flammable.
Explosive properties	: May form combustible dust concentrations in air.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 230.8 °C (According ACD Labs)
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 4 (1% aq. sol)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Soluble in ethanol. Moderately soluble in water. Organic solvent: 2.1 g/100ml DMSO (MEDCHEM EXPRESS)
Partition coefficient n-octanol/water (Log Kow)	: 3.62 estimated by KOWWIN v1.67. Trimebutine base
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1.104 g/cm <sup>3</sup> (According ACD/LABS)
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

Minimum ignition energy	: ≈ 3-4 mJ
Dust Cloud minimum Flammability Temperature	: 380 °C
Explosion Class	: St3
Explosion Severity Factor Kmax (bar.m/s)	: 332
Explosivity Pmax	: 9.2 bar.g
Layer Minimum flammability Temperature	: >400 °C

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No additional information available

#### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

# TRIMEBUTINE MALEATE

## Safety Data Sheet

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

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

Avoid dust formation. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides.

## SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified  
Acute toxicity (dermal) : Not classified  
Acute toxicity (inhalation) : Not classified

#### TRIMEBUTINE MALEATE (34140-59-5)

LD50 oral rat	> 5000 mg/kg Drugs in Japan, -(752), 1990 [Pubchem: <a href="https://pubchem.ncbi.nlm.nih.gov/compound/5388977#section=Toxicity">https://pubchem.ncbi.nlm.nih.gov/compound/5388977#section=Toxicity</a> ]
LD50 oral	3230 mg/kg oral mouse, Drugs in Japan, -(752), 1990 [Pubchem: <a href="https://pubchem.ncbi.nlm.nih.gov/compound/5388977#section=Toxicity">https://pubchem.ncbi.nlm.nih.gov/compound/5388977#section=Toxicity</a> ]
LD50, intraperitoneal, rat	365 mg/kg (Iyakuhin Kenkyu. Study of Medical Supplies, 15(688), 1984)
LD50, subcutaneous, rat	mg/kg (Iyakuhin Kenkyu. Study of Medical Supplies, 15(688), 1984)
LD50, intravenous, rat	23400 mg/kg (Drugs in Japan, -(752), 1990)

Skin corrosion/irritation : Not classified  
pH: 4 (1% aq. sol)  
Additional information : Based on available data, the classification criteria are not met  
Serious eye damage/irritation : Not classified  
pH: 4 (1% aq. sol)  
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 (Based on available data, the classification criteria are not met)  
Additional information : Based on available data, the classification criteria are not met

#### TRIMEBUTINE MALEATE (34140-59-5)

NOAEL (animal/male, F0/P)	1000 mg/kg/day via oral . Rat. Reproductive and fertility maximum dose (No effects at maximum dose)
NOAEL (animal/male, F1)	200 mg/kg/day via oral .Rabbit. Reproductive and fertility maximum dose (No effects at maximum dose)

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

# TRIMEBUTINE MALEATE

## Safety Data Sheet

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

### 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

#### 11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

## SECTION 12: Ecological information

### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified  
Hazardous to the aquatic environment, long-term (chronic) : Not classified

### 12.2. Persistence and degradability

#### TRIMEBUTINE MALEATE (34140-59-5)

Persistence and degradability	Not readily biodegradable. Not established.
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### 12.3. Bioaccumulative potential

#### TRIMEBUTINE MALEATE (34140-59-5)

Bioconcentration factor (BCF REACH)	121.3 estimated by BCFWIN v.2.17. Trimebutine base
Partition coefficient n-octanol/water (Log Kow)	3.62 estimated by KOWWIN v1.67. Trimebutine base
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

#### TRIMEBUTINE MALEATE (34140-59-5)

Organic Carbon Normalized Adsorption Coefficient (Log Koc)	4.795 estimated by PCKOCWIN v. 1.66. Trimebutine base
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### 12.5. Results of PBT and vPvB assessment

No additional information available

### 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

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.  
Ecology - waste materials : Avoid release to the environment.

# TRIMEBUTINE MALEATE

## Safety Data Sheet

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

### 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

#### 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



# TRIMEBUTINE MALEATE

## Safety Data Sheet

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

### 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)

##### 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) : NG - Non-hazardous

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

# TRIMEBUTINE MALEATE

## Safety Data Sheet

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

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### 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.

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.