TRIMEBUTINE BASE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 5/21/2019 Revision date: 9/26/2023 Supersedes version of: 5/21/2019 Version: 2.0

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

1.1. Product identifier

Product form	:	Substance
Trade name	:	TRIMEBUTINE BASE
Chemical name	:	2-(dimethylamino)-2-phenylbutyl 3,4,5-trimethoxybenzoate
IUPAC name	:	2-(dimethylamino)-2-phenylbutyl 3,4,5-trimethoxybenzoate
EC-No.	:	254-309-2
CAS-No.	:	39133-31-8
Product code	:	78500
Type of product	:	Active Ingredient for Medicinal / Pharmaceutical Use
Formula	:	C22H29NO5
Synonyms	:	2-(dimethylamino)-2-phenylbutyl 3,4,5-trimethoxybenzoate; Trimebutine Base
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

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.
Roma, 8 - P.I. Cova Solera
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

Manufacturer
MOEHS CANTABRA, S.L.
Pol. Ind. Requejada
39313 Polanco
Spain
T +34 942 131 045 - F +34 942 82 43 98
hse@moehs.com

1.4. Emergency telephone number

Emergency number	:	+34 93 586 05 20 (9:00 - 17:00)

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
Acute toxicity (dermal), Category 4	H312
Acute toxicity (inhalation:gas) Category 4	H332
Hazardous to the aquatic environment – Chronic Hazard, Category 4	H413

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

Adverse physicochemical, human health and environmental effects

Dust may form explosive mixture in air.

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+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled.
H413 - May cause long lasting harmful effects to aquatic life.

Precautionary statements (CLP) : P261 - Avoid breathing dust.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P271 - Use only outdoors or in a well-ventilated area.
P273 - Avoid release to the environment.
P280 - Wear eye protection, protective gloves, protective clothing.
P301+P312 - IF SWALLOWED: Call doctor, a POISON CENTER if you feel unwell.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P330 - Rinse mouth.
P362+P364 - Take off contaminated clothing and wash it before reuse.
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

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
TRIMEBUTINE BASE	CAS-No.: 39133-31-8 EC-No.: 254-309-2	≈ 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

Explosion hazard : Avoid raising powdered material due to explosion hazard.
Hazardous decomposition products in case of fire : Carbon monoxide. Nitrogen oxides. Carbon dioxide.

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 : Avoid contact with skin and eyes. 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 : Avoid dust formation. 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.
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 : 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. Oxidizing agents.

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

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

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

Hand protection:
Wear protective gloves.

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

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

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	white.
Appearance	:	Dust.
Molecular mass	:	387.47 g/mol
Odour	:	characteristic.
Odour threshold	:	Not available
Melting point	:	129 – 133 °C
Freezing point	:	Not available
Boiling point	:	457.9 °C (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 °C (According ACD Labs)
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Soluble in ethanol. Moderately soluble in water. Water: 5.74 mg/l at 25 ºC [Predicted by T.E.S.T]
Partition coefficient n-octanol/water (Log Kow)	:	3.62 estimated by KOWWIN v1.67. Trimebutine base

Vapour pressure	:	1.1 mm Hg at 25 ° C (According ACD Labs)
Vapour pressure at 50°C	:	Not available
Density	:	1.1 g/cm³
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

Explosion Class	:	St2
Explosion Severity Factor Kmax (bar.m/s)	:	213
Explosivity Pmax	:	8.2 bar

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.

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)	:	Harmful if swallowed.
Acute toxicity (dermal)	:	Harmful in contact with skin.
Acute toxicity (inhalation)	:	Harmful if inhaled.

TRIMEBUTINE BASE (39133-31-8)	
LD50 oral rat	≈ 450.24 mg/kg Predicted by T.E.S.T Toxicity estimation Software tool

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 (Based on available data, the classification criteria are not met)
Additional information : Based on available data, the classification criteria are not met

TRIMEBUTINE BASE (39133-31-8)	
NOAEL (animal/male, F0/P)	≈ 1000 mg/kg mg/kg/day via oral . Rat. Reprodductive and fertility maximum dose (No effects at maximum dose) [TRIMEBUTINE MALEATE]
NOAEL (animal/male, F1)	≈ 200 mg/kg mg/kg/day via oral .Rabbit. Reprodductive and fertility maximum dose (No effects at maximum dose) [TRIMEBUTINE MALEATE]

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

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) : May cause long lasting harmful effects to aquatic life.

TRIMEBUTINE BASE (39133-31-8)	
LC50 - Fish [1]	≈ 3.43 mg/l [Predicted by T.E.S.T] fathead minnow
EC50 - Crustacea [1]	≈ 5.42 mg/l [Predicted by T.E.S.T] DAPHNIA MAGNA

12.2. Persistence and degradability

TRIMEBUTINE BASE (39133-31-8)	
Persistence and degradability	Not readily biodegradable. Not established.

12.3. Bioaccumulative potential

TRIMEBUTINE BASE (39133-31-8)	
Bioconcentration factor (BCF REACH)	≈ 2.084 Bioaccumulation Estimates from Log Kow (BCFWIN v2.17) (BCF = 121.3)
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 BASE (39133-31-8)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	4.795 estimated by PCKOCWIN v. 1.66. Trimebutine base

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.

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

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

Denmark

Danish National Regulations	:	Pregnant/breastfeeding women working with the product must not be in direct contact with the product

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 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 4	Hazardous to the aquatic environment – Chronic Hazard, Category 4
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H413	May cause long lasting harmful effects to aquatic life.

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.