

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

Product form	: Substance
Trade name	: MEPIVACAINE HYDROCHLORIDE
Chemical name	: N-(2,6-Dimethylphenyl)-1-methyl-2-piperidinecarboxamide hydrochloride
EC-No.	: 217-023-9
CAS-No.	: 1722-62-9
Product code	: 75410
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C15H22N2O.HCl
Synonyms	: Carbocaine monohydrochloride ; Mepivacaine monohydrochloride ; N-(2,6-dimethylphenyl)-1-methyl, monohydrochloride
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: SMILES: CN1CCCCC1C(=O)NC1=C(C)C=CC=C1C.Cl

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	: Industrial For professional use only
Use of the substance/mixture	: Local anesthetic
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**Supplier**

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 CATALANA, S.L.
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08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

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]**

Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Signal word (CLP)	: -
Hazard statements (CLP)	: H412 - Harmful to aquatic life with long lasting effects.

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Precautionary statements (CLP) : P271 - Use only outdoors or in a well-ventilated area.
P280 - Wear eye protection, protective gloves, face protection.
P261 - Avoid breathing dust.
P262 - Do not get in eyes, on skin, or on clothing.
P270 - Do not eat, drink or smoke when using this product.
P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 - Get medical advice/attention if you feel unwell.
P273 - Avoid release to the environment.
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 : Dust may form explosive mixture in air.

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
MEPIVACAINE HYDROCHLORIDE	CAS-No.: 1722-62-9 EC-No.: 217-023-9	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. 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.

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.

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Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

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.
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 : Clear up rapidly by scoop or vacuum.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Do not allow to enter drains or water courses.

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. Provide good ventilation in process area to prevent formation of vapour.
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 in a well-ventilated place. Store at room temperature. Keep container closed when not in use.
Incompatible products : Strong bases. Strong acids.
Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

MEPIVACAINE HYDROCHLORIDE (1722-62-9)	
USA - ACGIH - Occupational Exposure Limits	
ACGIH OEL TWA	0.3 mg/m ³ external link : USP SDS
ACGIH OEL STEL	3 mg/m ³ external link : USP SDS

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:

Ensure good ventilation of the work station. Dust extraction (suction). Do not breathe dust. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Provide local exhaust or general room ventilation.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure. Safety glasses. Gloves. Wear respiratory protection.

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	Characteristics	Standard
Safety glasses	Dust, Fine dust	With side shields	EN 166

8.2.2.2. Skin protection

Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Latex, Polyvinylchloride (PVC), Fluoroelastomer (FKM), Neoprene rubber (HNBR), Nitrile rubber (NBR), Polyvinylalcohol (PVA), Butyl rubber, Natural rubber	EN ISO 374

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8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P3	Short term exposure, Long term exposure, Mist formation, Dust protection, Protection for Solid particles	EN 149

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment. Avoid creating or spreading dust.

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	: 282.8 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 262 – 264 °C
Freezing point	: Not available
Boiling point	: 383 °C 760 mmHg
Flammability	: Flammable solid.
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	: 185.5 °C
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 5 (1 % Sol. Water)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Soluble in water.
Partition coefficient n-octanol/water (Log Kow)	: 1.95 Exper. Ref. Hansch et al. (1995)
Partition coefficient n-octanol/water (Log Pow)	: 1.96 (estimated ACDLAB)
Vapour pressure	: < 0.0000001 kPa
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

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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 : 70-80 mJ
Additional information : Layer Minimum flammability Temperature : >400°C.
Dust Cloud minimum Flammability Temperature : 380°C.
Explosion Severity Factor K_{max} (bar.m/s) : 179.
Explosion Class : St1

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

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

fume. Carbon monoxide. Carbon dioxide.

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

MEPIVACAINE HYDROCHLORIDE (1722-62-9)	
LD50 oral rat	> 5000 mg/kg
LD50, subcutaneous, rat	500 mg/kg
LD50, subcutaneous, mouse	280 mg/kg
LD50, intravenous, mouse	32 mg/kg

Skin corrosion/irritation : Not classified
pH: 5 (1 % Sol. Water)
Additional information : Based on available data, the classification criteria are not met
Serious eye damage/irritation : Not classified
pH: 5 (1 % Sol. Water)
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

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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

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.

MEPIVACAINE HYDROCHLORIDE (1722-62-9)

EC50 - Crustacea [1]	18.5 mg/l [Mepivacaine base; Predicted by T.E.S.T]
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12.2. Persistence and degradability

MEPIVACAINE HYDROCHLORIDE (1722-62-9)

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

MEPIVACAINE HYDROCHLORIDE (1722-62-9)

Bioconcentration factor (BCF REACH)	6.331 (Estimated by BCFWIN V.2.17)
Partition coefficient n-octanol/water (Log Pow)	1.96 (estimated ACDLAB)
Partition coefficient n-octanol/water (Log Kow)	1.95 Exper. Ref. Hansch et al. (1995)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

MEPIVACAINE HYDROCHLORIDE (1722-62-9)

Organic Carbon Normalized Adsorption Coefficient (Log Koc)	3.231 (Estimated by PCKOCWIN)
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12.5. Results of PBT and vPvB assessment

MEPIVACAINE HYDROCHLORIDE (1722-62-9)

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

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

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

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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)

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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

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:

Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
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.