

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

Product form	: Substance
Trade name	: PRILOCAINE BASE
IUPAC name	: N-(2-methylphenyl)-2-(propylamino)-Propanamide
EC-No.	: 211-957-0
CAS-No.	: 721-50-6
Product code	: 77970
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C13H20N2O
Synonyms	: N-(2-methylphenyl)-2-(propylamino)-Propanamide / O-Methyl-Alpha-propylamina propionanilide
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: CCCNC(C)(=O)NC1=CC=CC=C1C

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

Main use category	: Industrial use, Professional use, Medicinal use, API
Industrial/Professional use spec	: Laboratory activities Active Ingredient for Medicinal / Pharmaceutical Use For professional use only Industrial
Use of the substance/mixture	: Anesthetics, Local Anesthetics. Prilocaine binds to the intracellular surface of sodium channels which blocks the subsequent influx of sodium into the cell. Action potential propagation and nerve function is, therefore, prevented. This block is reversible and when the drug diffuses away from the cell, sodium channel function is restored and nerve propagation returns.
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

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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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Safety Data Sheet

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

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
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
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

Harmful if swallowed.

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.

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

H413 - May cause long lasting harmful effects to aquatic life.

Precautionary statements (CLP)

: P264 - Wash hands, forearms and face thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P280 - Wear eye protection, protective gloves, face protection, protective clothing.

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

P302+P352 - IF ON SKIN: Wash with plenty of water.

P332+P313 - If skin irritation occurs: Get medical advice/attention.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

P501 - Dispose of contents/container to an approved waste disposal plant.

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	%
PRILOCAINE BASE	CAS-No.: 721-50-6 EC-No.: 211-957-0	100

3.2. Mixtures

Not applicable

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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	: Wash with plenty of water/.... Take off contaminated clothing. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth out with water. Do not induce vomiting. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects	: If you feel unwell, seek medical advice.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Harmful if swallowed.

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	: 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	: fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides. Toxic fumes may be released.
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5.3. Advice for firefighters

Precautionary measures fire	: Stop leak if safe to do so. 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. Avoid contact with skin and eyes.
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6.1.1. For non-emergency personnel

Protective equipment	: Breathing equipment.
Emergency procedures	: Evacuate unnecessary personnel. Avoid breathing dust, mist, vapours. Avoid contact with skin and eyes.
Measures in case of dust release	: Dust formation: dust mask.

6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection. Use personal protective equipment as required. Protective gloves. Dust/aerosol mask. Safety glasses.
Emergency procedures	: Ventilate area. Shovel or sweep up and put in a closed container for disposal. Stop leak if safe to do so.

6.2. Environmental precautions

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

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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.
- Other information : Dispose of materials or solid residues at an authorized site.

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

- Precautions for safe handling : Avoid breathing dust, mist, vapours. 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. Separate working clothes from town clothes. Launder separately.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep away from ignition sources. Keep container closed when not in use. Keep container tightly closed. Keep only in the original container in a cool, well ventilated place away from : Oxidizing agent, Heat sources, Direct sunlight.
- Incompatible products : Strong bases. Strong acids.
- Incompatible materials : Sources of ignition. Direct sunlight.
- Storage temperature : ≤ 25 °C
- Storage area : Store in a well-ventilated place. Store away from heat.

7.3. Specific end use(s)

Pharmaceuticals. 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:

Ensure good ventilation of the work station. Local exhaust or breathing protection. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Breathing equipment.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure. Gloves. Safety glasses. Dust/aerosol mask with filter type P3.

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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

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

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	Latex, Polyvinylalcohol (PVA), Polyvinylchloride (PVC), Natural rubber	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:

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

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Molecular mass	: 220.31 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 36 – 39 °C
Freezing point	: Not available
Boiling point	: 361.6±25.0 °C at 760 mmHg [predicted by ACD/Labs] ; 378.65 °C (Adapted Stein & Brown method)
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 134.3±23.3 °C [predicted by ACD/Labs]
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 4.5 – 6.5
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 541 mg/l [25°C]
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 2.11 According United States National Library of Medicine (CHEMIDPLUS) ; 1.87 According ALOGPS
Vapour pressure	: 2.13E-005 mmHg (Modified Grain method)
Vapour pressure at 50°C	: Not available
Density	: 1.0±0.1 g/cm3 [Predicted by 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

No additional information available

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.

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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) : Harmful if swallowed.
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

PRILOCAINE BASE (721-50-6)

LD50 oral rat	300 – 2000 mg/kg (OECD Guideline 423) The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.
LD50, subcutaneous, mouse	519 mg/kg ((Nippon Yakurigaku Zasshi. Japanese Journal of Pharmacology. Vol. 61, Pg.))
LD50, intraperitoneal, mouse	231 mg/kg ((Nippon Yakurigaku Zasshi. Japanese Journal of Pharmacology. Vol. 61, Pg.))
LD50, intravenous, mouse	59.9 mg/kg ((Nippon Yakurigaku Zasshi. Japanese Journal of Pharmacology. Vol. 61, Pg.))

Skin corrosion/irritation : Causes skin irritation.
pH: 4.5 – 6.5
Additional information : Based on available data, the classification criteria are not met
Serious eye damage/irritation : Causes serious eye irritation.
pH: 4.5 – 6.5
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

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

PRILOCAINE BASE (721-50-6)	
LC50 - Fish [1]	188 mg/l
EC50 - Crustacea [1]	33.1 mg/l

12.2. Persistence and degradability

PRILOCAINE BASE (721-50-6)	
Persistence and degradability	May cause long-term adverse effects in the environment. Minimally biodegradable % biodegradation < 10 % CO ₂ formation relative to the theoretical value (28 d) (OECD 301B; ISO 9439; 92/69/EEC, C.4-C) (aerobic, activated sludge, domestic).

12.3. Bioaccumulative potential

PRILOCAINE BASE (721-50-6)	
BCF - Fish [1]	1 [pH 5.5; Predicted by ACD/Labs]
Partition coefficient n-octanol/water (Log Pow)	2.11 According United States National Library of Medicine (CHEMIDPLUS) ; 1.87 According ALOGPS
Bioaccumulative potential	Not established.

12.4. Mobility in soil

PRILOCAINE BASE (721-50-6)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.79 [pH 5.5; Predicted by ACD/Labs]

12.5. Results of PBT and vPvB assessment

PRILOCAINE BASE (721-50-6)	
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.

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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

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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 : 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

PRILOCAINE BASE

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

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
SDS	Safety Data Sheet
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
NOAEL	No-Observed Adverse Effect Level
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

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 4	Hazardous to the aquatic environment – Chronic Hazard, Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H413	May cause long lasting harmful effects to aquatic life.
Skin Irrit. 2	Skin corrosion/irritation, Category 2

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.