

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

Product form	: Substance
Trade name	: TRIAMTERENE
Chemical name	: 6-phenyl-2,4,7-triaminopteridine
IUPAC name	: 6-phenyl-2,4,7-triaminopteridine
EC-No.	: 206-904-3
CAS-No.	: 396-01-0
Product code	: 78610
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C ₁₂ H ₁₁ N ₇
Synonyms	: Triamterene, Triamteren, 6-phenylpteridine-2,4,7-triamine
Other means of identification	: SMILES: NC1=C(N=C(C3=CC=CC=C3)C(N)=N2)C2=NC(N)=N1

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

Main use category	: Professional use, Industrial use, API
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use For professional use only Industrial
Use of the substance/mixture	: Diuretic; Chemical Intermediate
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.
Cesar Martinell i Brunet, 12 A P.I. Rubi Sud
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]**

Acute toxicity (oral), Category 4	H302
Carcinogenicity, Category 2	H351
Specific target organ toxicity – Repeated exposure, Category 2	H373
Full text of H- and EUH-statements: see section 16	

Adverse physicochemical, human health and environmental effects

No additional information available

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

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H302 - Harmful if swallowed.

H351 - Suspected of causing cancer.

H373 - May cause damage to organs (kidneys) through prolonged or repeated exposure.

Precautionary statements (CLP) :

P202 - Do not handle until all safety precautions have been read and understood.

Local exhaust is needed at source of dust.

P260 - Do not breathe dust.

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

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

P280 - Wear protective clothing, protective gloves.

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

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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

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

P314 - Get medical advice/attention if you feel unwell.

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.

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
TRIAMTERENE	CAS-No.: 396-01-0 EC-No.: 206-904-3	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). If medical advice is needed, have product container or label at hand. Suspected of causing cancer.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

First-aid measures after skin contact : Wash with plenty of water/.... Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention.

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. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.

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

- Symptoms/effects : Causes damage to organs.
Symptoms/effects after ingestion : May be harmful if swallowed and enters airways. 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

Never give anything by mouth to an unconscious person. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Carbon dioxide. Sand. Foam.
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. Toxic fumes may be released. Carbon monoxide. Carbon dioxide.

5.3. Advice for firefighters

- Precautionary measures fire : Stop leak if safe to do so.
Firefighting instructions : Eliminate all ignition sources if safe to do so. Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. 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 : No open flames. No smoking. No flames, no sparks. Eliminate all sources of ignition. Use special care to avoid static electric charges.

6.1.1. For non-emergency personnel

- Emergency procedures : Avoid contact with skin and eyes. Do not breathe dust. Ventilate spillage area. Evacuate unnecessary personnel.
Measures in case of dust release : Dust formation: dust mask.

6.1.2. For emergency responders

- Protective equipment : EN 136. EN 148. EN 1149-1. EN 13034. EN 14605. Equip cleanup crew with proper protection.
Emergency procedures : Ventilate confined spaces before entering. Shovel or sweep up and put in a closed container for disposal. Ventilate area.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

- For containment : Collect spillage.
Methods for cleaning up : Large spills: scoop solid spill into closing containers. Minimise generation of dust. On land, sweep or shovel into suitable containers. Store away from other materials.
Other information : Dispose of materials or solid residues at an authorized site.

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.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Strong acids, strong bases and oxidation agents.
Precautions for safe handling	: Do not handle until all safety precautions have been read and understood. Ensure good ventilation of the work station. Do not get in eyes, on skin, or on clothing. Wear personal protective equipment. Avoid breathing dust, fume, gas, vapours, mist, spray. Avoid dust formation. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Prevent the build-up of electrostatic charge. No open flames. No smoking.
Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling. Wash contaminated clothing before reuse. Separate working clothes from town clothes. Launder separately.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Provide local exhaust or general room ventilation. Comply with applicable regulations.
Storage conditions	: Store at room temperature. Store in a well-ventilated place. Store in a dry place. Store in original container. Keep away from ignition sources. Keep container tightly closed.
Incompatible products	: Strong acids. Oxidizing agent. Strong bases.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage area	: Store in a well-ventilated place.
Special rules on packaging	: Store in a closed container.

7.3. Specific end use(s)

Pharmaceuticals.

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: 3 (0.01 - 0.1 mg/m³)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. 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:

Avoid all unnecessary exposure. Safety glasses. Gloves. Dust/aerosol mask. Protective clothing.

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Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Skin and body protection	
Type	Standard
Tyvek® Gown/Coveralls	EN 13034

Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Polyvinylalcohol (PVA), Natural rubber, Polyvinylchloride (PVC), Latex	EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Full face mask, Powered mask, Powered hoods/helmets	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 when using this product. 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	: Yellow.
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 316 °C
Freezing point	: Not available
Boiling point	: Not available

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Flammability	: Dust could form explosive mixtures with air
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: ≈ 178 °C According to ACDLABS (Predicted)
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 48.2 mg/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 0.98
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 0.4 g/cm ³
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	: 22 mJ
Additional information	: Dust Cloud minimum Flammability Temperature : 860 °C. Layer Minimum flammability Temperature : Melt. Minimum Explosive Concentration : 150 g/m ³ . Explosivity Pmax : 8.2 bar·g. Explosion Severity Factor Kmax (bar·m/s) : 148 bar·m/s. Explosion Class : St1

SECTION 10: Stability and reactivity

10.1. Reactivity

Dust may form explosive mixture in air. The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

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

TRIAMTERENE (396-01-0)

LD50 oral rat	400 mg/kg
LD50, oral, mouse	285 mg/kg
LD50, intraperitoneal, rat	200 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 : Suspected of causing cancer.
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 : May cause damage to organs (kidneys) through prolonged or repeated exposure.
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,Harmful in contact with skin,Harmful if inhaled,Irritation: severely irritant to eyes,Irritation: may cause irritation to the respiratory system,Severely irritant to skin
Other information : Likely routes of exposure: inhalation, skin and eye.

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

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LC50 - Fish [1]	> 13 mg/l [Rainbow trout; Measured]
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TRIAMTERENE (396-01-0)	
EC50 - Crustacea [1]	> 10 mg/l [Water flea; Measured]
EC50 72h - Algae [1]	14 mg/l [Green algae (Selenastrum capricornutum); Measured]
LOEC (chronic)	> 10 mg/l [Water flea (Ceriodaphnia dubia); 7 days Nominal]
NOEC chronic crustacea	10 mg/l [Static test; Water flea]

12.2. Persistence and degradability

TRIAMTERENE (396-01-0)	
Persistence and degradability	Not established.
Biodegradation	50 % [Aerobic biodegradation-inherent; 14 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge]

12.3. Bioaccumulative potential

TRIAMTERENE (396-01-0)	
Partition coefficient n-octanol/water (Log Pow)	0.98
Bioaccumulative potential	Not established.

12.4. Mobility in soil

TRIAMTERENE (396-01-0)	
Mobility in soil	1.95 [Adsorption; Measured, pH 7; Sludge/biomass distribution coefficient - log Kd]

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

Additional information : Industrial waste.

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

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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

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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

Denmark

Classification remarks : Emergency management guidelines for the storage of flammable liquids must be followed

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product
Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK) : LK 6.1 - Toxic materials

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

BCF	Bioconcentration factor
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Abbreviations and acronyms:

CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IATA	International Air Transport Association
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

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
Carc. 2	Carcinogenicity, Category 2
H302	Harmful if swallowed.
H351	Suspected of causing cancer.
H373	May cause damage to organs through prolonged or repeated exposure.
STOT RE 2	Specific target organ toxicity – Repeated exposure, 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.