

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

CETRIMIDUM

EN

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Cetrimide
Cetrimidum
Cetrimide
Cétrimide
Cetrimid
N° CAS: 1119-97-7
N° EC: 214-291-9

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV
Oostmalsebaan 1c (unit 5)
2960 Sint-Lenaarts
Belgium
Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

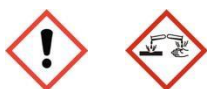
Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Acute Tox. 4	H312
Skin Corr. 1B	H314
Eye Dam. 1	H318
Acute Tox. 4	H332

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger
Irritant
Corrosive

Hazard statements:

H302 Harmful if swallowed.

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H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
Precautionary statements:	
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P321	Specific treatment (see on this label).
P322	Specific measures (see on this label).
P362	Take off contaminated clothing.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501	Dispose of contents/container to a waste disposal facility in accordance with local, regional, national and/or international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Cetrimide
IUPAC name:	trimethyl(tetradecyl)azanium;bromide
Synonyms:	Tetradonium bromide Tetradecyltrimethylammonium bromide Alkyltrimethylammonium bromide Trimethyltetradecylammonium bromide Myristyltrimethylammonium bromide
N° CAS:	1119-97-7
N° EC:	214-291-9
Molecular Formula:	C ₁₇ H ₃₈ BrN
Content:	96.0 per cent to 101.0 per cent of alkyltrimethylammonium bromides, calculated as (C ₁₇ H ₃₈ BrN ; M _r 336.4) (dried substance). Cetrimide consists of trimethyltetradecylammonium bromide (C ₁₇ H ₃₈ BrN ; M _r 336.4) and may contain smaller amounts of dodecyl- and hexadecyl-trimethylammonium bromides.

3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

SECTION 4: FIRST AID MEASURES

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4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water mist. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health (NH_x and Br_2) may be produced.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from entering sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For exposure control and personal protective measures, see section 8.

Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

For emergency responders

For exposure control and personal protective measures, see section 8.

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Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

6.2 Environmental precautions

Prevent release to the environment.

Prevent entry into sewers and watercourses.

If product enters drains or public waterways, notify authorities.

6.3 Methods and material for containment and cleaning up

Store away from other materials.

If on the ground, sweep or scoop (shovel or similar) into suitable containers.

Limit dust production.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Wash thoroughly after handling.

Do not eat, drink or smoke while handling this product.

Personal protection:

Not available.

Technical protective measures:

Ensure good ventilation of the processing area to avoid formation of vapour.

Handling:

Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Keep only in the original container in a cool, well-ventilated place.

Keep container closed when not in use.

Storage – away from:

Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection:

Protective face shields and safety goggles according to EN166.

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Skin protection:	Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.
Respiratory protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).
Thermal hazards:	Not determined.
Environmental exposure control	
Not available.	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, voluminous, free-flowing powder.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	4.0 – 6.0 (100 g/l)
Melting/freezing point:	> 245 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in alcohol.
Solubility in water:	Freely soluble in water. 500 g/l (20 °C)
Partition coefficient (n-octanol/water):	LogPow 2.26 (20 °C)
Auto-ignition temperature:	Not available.
Decomposition temperature:	> 230 °C
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular weight: 364.46 g/mol
Density (25 °C): 0.374 g/ml
VOC (Directive 199/13/EC): 0.00
VOC (volatile carbon): 0.00

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions. Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Decomposition by heat may produce toxic fumes of Br₂, HBr and NH_x.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity (LD ₅₀ , rat): 410 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	May cause cancer.
Reproductive toxicity:	Suspected of impairing fertility.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Irritations. Causes serious eye damage.
Skin contact:	Irritations, sensitisation, allergic reaction. Harmful in contact with skin. Causes severe skin burns.
Inhalation:	Irritation of the respiratory tract. Harmful if inhaled.
Ingestion:	Central nervous system effects, anxiety, spasms, cardiovascular disorders, breathing difficulties. Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

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12.1 Toxicity

Not established.

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

The substance does not meet the criteria to be identified as a PBT or vPvB according to Annex XIII of the REACH Regulation.

12.6 Other adverse effects

Avoid release into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.6 Special precautions for user

It is not dangerous in transport.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

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14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Risk phrases:

Irritant Corrosive

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

R35 Causes severe burns.

R41 Risk of serious damage to eyes.

Safety phrases:

S23 Do not breathe dust/fume/gas/mist/vapours/spray.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S27 Take off immediately all contaminated clothing.

S28 After contact with skin, wash immediately with plenty of water.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

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Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

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