

CROTAMITONUM

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

1.1 Product identifier

Product name:	Crotamiton Crotamitonum Crotamiton Crotamiton Crotamiton
N° CAS:	483-63-6
N° EC:	207-596-3

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk 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.centreatipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Skin Irr. 2	H315
Skin Sens. 1	H317
Eye Irr. 2	H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



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Signal word(s):	Attention
Hazard statements:	
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+312+330	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302+352	IF ON SKIN: Wash with soap and water.
P305+338+351	IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P308+313	IF exposed or concerned: Get medical advice/attention.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Crotamiton
IUPAC name:	N-Ethyl-N-(2-methylphenyl)but-2-enamide
Synonyms:	Eurax Crotalgin Veteusan
N° CAS:	483-63-6
N° EC:	207-596-3
Molecular Formula:	C ₁₃ H ₁₇ NO
Content:	Sum of the (E)- and (Z)-isomers: 96.0 per cent to 102.0 per cent. (Z)-isomer: maximum 15.0 per cent.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Remove to a fresh air area and get medical attention if necessary.
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After skin contact:	Remove all contaminated clothing and flush skin, hair etc. with running water.
After eye contact:	Immediately flush eyes with plenty of water and get medical attention.
After ingestion:	Get medical attention.

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 chemical powder, CO ₂ , water.
Unsuitable extinguishing media:	Heavy water stream.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:	General fire hazards: combustible. Fire incompatibility: Avoid contamination.
Protection against fire:	In the event of a fire, wear full protective clothing, chemical protective goggles, gloves and appropriate respirator containing type A filter of sufficient capacity.
Hazardous combustion products:	Incomplete combustion will generate poisonous CO, CO ₂ , and other toxic gases.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove all sources of ignition. Ventilate the area where the leak or spill occurred. Wear appropriate personal protective equipment as specified in section 8, and isolate the hazard area. Keep unnecessary and unprotected personnel from entering.

For emergency responders

Remove all sources of ignition. Ventilate the area where the leak or spill occurred. Wear appropriate personal protective equipment as specified in section 8, and isolate the hazard area. Keep unnecessary and unprotected personnel from entering.

6.2 Environmental precautions

Do not discharge into sewer or waterways.

6.3 Methods and material for containment and cleaning up

Carefully sweep up material into an appropriate container and save for reclamation or disposal.

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6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Use in a well ventilated area. When handling do not eat, drink or smoke.
Personal protection:	Wear protective equipment. Avoid personal contact including inhalation.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in a well closed container.
Conditions for safe storage, including any incompatibilities:	Temperature should not be more than 40 °C. Relative humidity should not be more than 75 %.
Storage – away from:	Store protected from light.

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

Ventilation system: A system of local and/or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area.

Individual protection measures

Eye/face protection:	Use chemical safety goggles and/or a full face shield where splashing is possible. Provide an eye wash fountain and quick-drench facilities in the work area.
Skin protection:	Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.
Hand protection:	Wear gloves.
Respiratory protection:	Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate.

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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:	Colourless or pale yellow, oily liquid.
Odour:	Almost odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
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:	1.006 to 1.011
Solubility:	Miscible with ethanol (96 per cent). At low temperatures it may partly or completely solidify.
Solubility in water:	Slightly soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

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Not available.

10.2 Chemical stability

Stable under normal conditions in tightly closed containers, protected from light.

10.3 Possibility of hazardous reactions

Hazardous polymerisation: Will not occur.

10.4 Conditions to avoid

Incompatibles. Light (sunlight included). Heat.

10.5 Incompatible materials

Avoid reaction with oxidising agents.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD50 (rat): 1 500 mg/kg Intraperitoneal LD50 (rat): 318 mg/kg Subcutaneous LD50 (rat): 1 630 mg/kg Oral LD50 (mouse): 1 600 mg/kg Intraperitoneal LD50 (mouse): 395 mg/kg Subcutaneous LD50 (mouse) : 1 393 mg/kg
Skin corrosion/irritation:	May cause skin irritation. May be harmful by skin absorption.
Serious eye damage/irritation:	May cause eye irritation.
Respiratory/skin sensitisation:	Sensitisation possible through skin contact.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
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:	May cause eye irritation.
Skin contact:	May cause skin irritation. May be harmful by skin absorption.
Inhalation:	May be harmful by inhalation.



MATERIAL SAFETY DATA SHEET

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

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Ingestion: May be harmful by ingestion.
Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Persistence: water, air: high.

12.3 Bioaccumulative potential

Bioaccumulation: low.

12.4 Mobility in soil

Mobility: medium.

12.5 Results of PBT and vPvB assessment

Not applicable.

12.6 Other adverse effects

Do not discharge into sewers or waterways.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Whatever can't be saved for recovery or recycling, should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations.

Dispose of container and unused contents in accordance with federal, state and local requirements.

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) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

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ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not available.

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

Not available.

14.8 Additional transport information

Although it is not regulated, the following storage conditions should be considered during transport:
Well closed container, protected from light.
Temperature should not be more than 40 °C.
Relative humidity should not be more than 75 %.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

Not applicable.

Safety phrases:

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

15.2 Chemical safety assessment

A chemical safety assessment 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

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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

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

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