

Material Safety Data Sheet

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

XYLOMETAZOLINI HYDROCHLORIDUM

EN

FORM-06-14-01 (V00)

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Version: 00



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

1.1 Product identifier

Product name: Xylometazoline hydrochloride
Xylometazolini hydrochloridum
Xylometazolinehydrochloride
Xylométazoline (chlorhydrate de)
Xylometazolinhydrochlorid

N° CAS: 1218-35-5

N° EC: 214-936-4

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. 3	H301
Eye Dam. 1	H318
Aquatic Chronic 3	H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H301	Toxic if swallowed.
H318	Causes serious eye damage.
H412	Harmful to aquatic life with long lasting effects.

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Precautionary statements:

P264	Wash hands and other exposed areas thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: immediately call a POISON CENTER or doctor/physician.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
P330	Rinse mouth.
P501	Dispose of contents/container to: Hazardous waste. Comply with applicable regulations.

Additional applicable label elements: Not applicable.

2.3 Other hazards

Other hazards not contributing to the classification: Exposure may produce an allergic reaction.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Xylometazoline hydrochloride
IUPAC name:	2-[(4- <i>tert</i> -butyl-2,6-dimethylphenyl)methyl]-4,5-dihydro-1 <i>H</i> -imidazole;hydrochloride
Synonyms:	Xylometazoline HCl Xylometazoline (hydrochloride)
N° CAS:	1218-35-5
N° EC:	214-936-4
Molecular Formula:	C ₁₆ H ₂₅ ClN ₂
Content:	99.0 per cent to 101.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	If you feel unwell, seek medical advice (show the label where possible). Immediately flush the contact area with plenty of water.
After inhalation:	Move to fresh air in case of accidental inhalation. Assure fresh air breathing. Obtain medical attention if breathing difficulty persists. If breathing is difficult, give oxygen.
After skin contact:	Rinse skin with water/shower. Wash with plenty of soap and water. Flush with water for 15 minutes. If skin irritation persists, take medical advice.
After eye contact:	Rinse with water while holding the eyes wide open. Contact lenses should be removed. Obtain medical attention if pain, blinking or redness persist. Continue to rinse eye with clean water for 20-30 minutes, retracting eyelids often.

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After ingestion: Rinse mouth out with water. The following symptoms may occur: (see section(s): 2, 4.2). If you feel unwell, seek medical advice. Do NOT induce vomiting.

Self-protection of the first aider: Use personal protective equipment (PPE).

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries: See section 2. Corrosive. Causes burns. Burning sensation. Pain.

Symptoms/injuries after inhalation: Respiratory, thoracic and mediastinal disorders. May cause shortness of breath, tightness of the chest, a sore throat and cough.

Symptoms/injuries after skin contact: Skin and subcutaneous tissue disorders. Skin corrosion/ irritation. Redness, pain.

Symptoms/injuries after eye contact: Direct contact may result in corneal injury. Redness, pain.

Symptoms/injuries after ingestion: Gastrointestinal disorders. Burns to the gastric/intestinal mucosa.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, carbon dioxide, dry powder, foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Fire hazard: Beware, risk of formation of toxic and corrosive gases.

5.3 Advice for firefighters

Surrounding fires: Dilute with water.

Protection against fire: Use normal individual fire protective equipment.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

General measures: Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Avoid any direct contact with the product. Evacuate unnecessary personnel. Causes burns. Avoid all contact with skin, eyes, or clothing. Do not breathe dust/fume/gas/mist/vapours/spray.

Protective equipment: See sections 7 and 8.

Emergency procedures: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Wear suitable protective clothing and gloves.

For emergency responders

General measures: Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Avoid any direct contact with the product. Evacuate unnecessary personnel. Causes burns. Avoid all contact with skin, eyes, or clothing. Do not breathe dust/fume/gas/mist/vapours/spray.

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6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Clean with water. Collect all waste in suitable and labelled containers and dispose according to local legislation.

6.4 Reference to other sections

See section(s): 8, 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Handle and open container with care. See section 8. Do not handle until all safety precautions have been read and understood. Avoid any direct contact with the product.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Handle in accordance with good industrial hygiene and safety procedures.

Additional hazards when processed: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Comply with applicable regulations.

Conditions for safe storage, including any incompatibilities:

To guarantee the quality and properties of the product, keep: dry, Keep in a cool, well ventilated place. Store in original container.

Incompatible products : Strong oxidizing agents.

Storage – away from:

Store protected from light. Store away from heat.

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

Ensure adequate ventilation, especially in confined areas.

Hygiene measures: When using do not eat, drink or smoke. Remove and wash contaminated clothing before re-use.

Provide regular cleaning of work area and clothing.

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Individual protection measures

Eye/face protection:	Chemical safety goggles required.
Skin protection:	Chemical-resistant gloves required.
Hand protection:	Long sleeved clothing.
Respiratory protection:	Protecting mask required.
Thermal hazards:	No information available.

Environmental exposure control

Do not allow material to contaminate ground water system.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Not applicable. See sections 2, 4.2, 8.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	317 - 329 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	> 100 °C
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 ethanol (96 per cent) and in methanol.
Solubility in water:	Freely soluble in water. > 100 mg/l
Partition coefficient (n-octanol/water):	Log P(o/w): 0.36 at 20 °C
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.

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SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

No additional information available.

10.3 Possibility of hazardous reactions

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

10.4 Conditions to avoid

No additional information available.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Toxic if swallowed. LD ₅₀ oral rat 230 mg/kg ATE (oral) 100,000 mg/kg
Skin corrosion/irritation:	Not classified.
Serious eye damage/irritation:	Causes serious eye damage.
Respiratory/skin sensitisation:	Not classified.
Germ cell mutagenicity:	Not classified.
Carcinogenicity:	Not classified.
Reproductive toxicity:	Not classified.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not classified.
STOT-repeated exposure:	Not classified.
Aspiration Hazard:	Not classified.
Other:	Potential adverse human health effects and symptoms: Avoid any direct contact with the product. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. See first aid section of this material safety data sheet.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye damage.
Skin contact:	Not available.
Inhalation:	Not available.

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Ingestion: Toxic if swallowed.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology - general See section 2. Hazardous waste. Use suitable disposal containers.

Ecology - water Soluble in water.

LC₅₀ fish 60.61 mg/l LC₅₀-96 h - fish

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Log Pow: 0.36 at 20 °C

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Regional legislation (waste): Dispose in a safe manner in accordance with local/national regulations.

Waste disposal recommendations: Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 2811
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), TOXIC SOLID, ORGANIC, N.O.S.
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 6.1
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

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14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : No information available.

14.6 Special precautions for user

Over land transport

Hazard identification number (Kemler No.): 60

Classification code (UN): T2

Tunnel restriction code: E

LQ: LQ09

Excepted quantities (ADR): E1

Transport by sea

Ship Safety Act: Toxic and infectious substances/Toxic substances.

MFAG-No: 154

Air transport

Civil Aeronautics Law: Toxic and infectious substances/Toxic substances.

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

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Toxic



Corrosive

Risk phrases:

R22 Harmful if swallowed.

R41 Risk of serious damage to eyes.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

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

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

S46 If swallowed, seek medical advice immediately and show this container or label.

S56 Dispose of this material and its container at hazardous or special waste collection point.

S61 Avoid release to the environment. Refer to special instructions/safety data sheets.

15.2 Chemical safety assessment

Not available.

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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

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

FAC SECUNDUM ARTEM NV

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