Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 28.10.2019
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Version number 24

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· **Trade name:** Xylometazoline Hydrochloride
Xylometazolini hydrochloridum

· **Article number:** 101203
· **CAS Number:**
1218-35-5
· **EC number:**
214-936-4
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the mixture** Pharma Active ingredients

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Fagron UK Ltd
4B Coquet St
Newcastle upon Tyne
England NE1 2QB
Tel. 0845 6522525

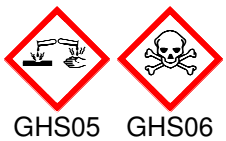
· **Further information obtainable from:**
Emergency response telephone number:
+44 (0) 845 652 2525
· **1.4 Emergency telephone number:**
Emergency response telephone number:
+44 (0) 845 652 2525

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Acute Tox. 3	H301	Toxic if swallowed.
Eye Dam. 1	H318	Causes serious eye damage.
Aquatic Chronic 3	H412	Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
· **Hazard pictograms**



GHS05 GHS06

· **Signal word** Danger
· **Hazard statements**
H301 Toxic if swallowed.
H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.
· **Precautionary statements**

P280	Wear eye protection / face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P321	Specific treatment (see on this label).

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Xylometazoline Hydrochloride
Xylometazolini hydrochloridum

(Contd. of page 1)

P330 Rinse mouth.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405 Store locked up.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.1 Chemical characterisation: Substances** Formula: C16H24N2*HCl Mr: 280.8
· **CAS No. Description**
1218-35-5 Xylometazoline Hydrochloride
Xylometazolini hydrochloridum
· **Identification number(s)**
· **EC number:** 214-936-4

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SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:**
Personal protection for the First Aider.
Immediately remove any clothing soiled by the product.
In case of irregular breathing or respiratory arrest provide artificial respiration.
· **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:**
Seek medical treatment.
Immediately wash with water and soap and rinse thoroughly.
· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing:**
Rinse out mouth and then drink plenty of water. Consult a doctor.
Induce vomiting and call for medical help.
Do not induce vomiting; call for medical help immediately.
· **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:**
Water spray
Fire-extinguishing powder
Carbon dioxide
Foam
Use fire extinguishing methods suitable to surrounding conditions.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Xylometazoline Hydrochloride
Xylometazolini hydrochloridum

(Contd. of page 2)

· **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
Carbon monoxide (CO)
Hydrogen chloride (HCl)
Nitrogen oxides (NOx)
· **5.3 Advice for firefighters**
· **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

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SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Use respiratory protective device against the effects of fumes/dust/aerosol.
Wear protective clothing.
Wear protective equipment. Keep unprotected persons away.
· **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
· **6.3 Methods and material for containment and cleaning up:**
Send for recovery or disposal in suitable receptacles.
Use neutralising agent.
Dispose contaminated material as waste according to item 13.
· **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

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SECTION 7: Handling and storage

· **7.1 Precautions for safe handling** Thorough dedusting.
· **Information about fire - and explosion protection:**
Dust explosion class: dust explosion class 3 (Kst-value > 300 bar m s-1).

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
· **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **8.1 Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:** Not required.
· **Additional information:** The lists valid during the making were used as basis.

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Xylometazoline Hydrochloride
Xylometazolini hydrochloridum

(Contd. of page 3)

· **8.2 Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes.
Avoid contact with the eyes and skin.
· **Respiratory protection:** Filter P2
· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Material of gloves**
Nitrile rubber, NBR
Chloroprene rubber, CR
Butyl rubber, BR
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
· **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Crystalline
Colour:	Whitish
· **Odour:**	Nearly odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	5-7

(Contd. on page 5)

Trade name: Xylometazoline Hydrochloride
Xylometazolini hydrochloridum

(Contd. of page 4)

· **Change in condition**	
Melting point/freezing point:	317-329 °C
Initial boiling point and boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gas):**	Product is not flammable.
· **Ignition temperature:**	430 °C
· **Decomposition temperature:**	> 225 °C
· **Auto-ignition temperature:**	Not determined.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapour pressure:**	Not applicable.
· **Density at 20 °C:**	0.5 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.
· **Evaporation rate**	Not applicable.
· **Solubility in / Miscibility with water at 20 °C:**	100 g/l
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· **9.2 Other information**	Freely sol. in H2O, EtOH 96% and MeOH.

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SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions**
Risk of dust explosion.
Develops toxic gases/fumes.
Reacts with acids, alkalis and oxidising agents.
Reacts with reducing agents.
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:**
Carbon monoxide and carbon dioxide
Hydrogen chloride (HCl)
Nitrogen oxides (NOx)

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Xylometazoline Hydrochloride
Xylometazolini hydrochloridum

(Contd. of page 5)

Poisonous gases/vapours

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity**
Toxic if swallowed.

· **LD/LC50 values relevant for classification:**		
Oral	LD50	122 mg/kg (Rat)
Inhalative	LC50/4 h	>0.47-<1.08 mg/l (Rat)

· **Primary irritant effect:**
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation**
Causes serious eye damage.
· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
LC50 (96h)	71 mg/l (Fish)
EC50 (48h)	5.63 mg/l (Daphnia)

· **12.2 Persistence and degradability** Heavily biodegradable
· **Other information:**
Test method: OECD 301 A (new version)
Method of analysis: DOC reduction
Degree of elimination : <10 % (28d).
Assessment: Poorly biodegradable.
· **12.3 Bioaccumulative potential**
Due to the distribution coefficient n-octanol/water an accumulation in organisms is not expected.
log Pow: 2,84
· **12.4 Mobility in soil** No further relevant information available.
· **Ecotoxical effects:**
· **Remark:** Harmful to fish
· **Remark:**
Aquatic plants:
Desmodesmus subspicatus EC50 (72h): 2,03 mg/l (OECD-guideline 201 static)
The statement of the toxic effect refers to the nominalconcentration.
Microorganisms / effect to activated sludge:
activated sludge EC20 (0.5h): ca. 90 mg/l (OECD-guideline 209 aerob)
The statement of the toxic effect refers to the nominalconcentration.

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Xylometazoline Hydrochloride
Xylometazolini hydrochloridum

(Contd. of page 6)

· **Additional ecological information:**
· **General notes:**
Water hazard class 3 (German Regulation) (Assessment by list): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
Danger to drinking water if even extremely small quantities leak into the ground.
Harmful to aquatic organisms
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

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SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Must be specially treated adhering to official regulations.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR, IMDG, IATA**	UN2811
· **14.2 UN proper shipping name**	
· **ADR**	2811 TOXIC SOLID, ORGANIC, N.O.S. (Xylometazoline Hydrochloride Xylometazolini hydrochloridum)
· **IMDG**	TOXIC SOLID, ORGANIC, N.O.S. (Xylometazoline Hydrochloride Xylometazolini hydrochloridum), MARINE POLLUTANT
· **IATA**	TOXIC SOLID, ORGANIC, N.O.S. (Xylometazoline Hydrochloride Xylometazolini hydrochloridum)

(Contd. on page 8)

Trade name: Xylometazoline Hydrochloride
Xylometazolini hydrochloridum

(Contd. of page 7)

· **14.3 Transport hazard class(es)**	
· **ADR**	
	
· **Class**	6.1 Toxic substances.
· **IMDG**	
	
· **Class**	6.1 Toxic substances.
· **Label**	6.1
· **IATA**	
	
· **Class**	6.1 Toxic substances.
· **Label**	6.1
· **14.4 Packing group**	
· **ADR, IATA**	II
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	Yes Symbol (fish and tree)
· **14.6 Special precautions for user**	Warning: Toxic substances.
· **Danger code (Kemler):**	60
· **EMS Number:**	F-A,S-A
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **Limited quantities (LQ)**	500 g
· **UN "Model Regulation":**	UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (XYLOMETAZOLINE HYDROCHLORIDE XYLOMETAZOLINI HYDROCHLORIDUM), 6.1, II

(Contd. on page 9)

Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Xylometazoline Hydrochloride
Xylometazolini hydrochloridum

(Contd. of page 8)

SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** Substance is not listed.
· **Seveso category** H2 ACUTE TOXIC
· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

· **National regulations:**

Class	Share in %
I	100.0

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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SECTION 16: Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

· **Department issuing SDS:**
Fagron UK
Quality Assurance
· **Contact:** quality@fagron.co.uk
· **Abbreviations and acronyms:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 3: Acute toxicity – Category 3
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
· *** Data compared to the previous version altered.**