

Xylometazoline hydrochloride

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 14/03/2012 Revision date: 28/02/2017

400963

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Xylometazoline hydrochloride
IUPAC name : 2-[4-(1,1-Dimethylethyl)-2,6-dimethylbenzyl]-4,5-dihydro-1H-imidazole hydrochloride
EC No : 214-936-4
CAS No : 1218-35-5
Product code : 400963
Formula : C₁₆H₂₅ClN₂
Synonyms : Otrivin
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

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 3

H301

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Acute toxicity (inhal.), Category 3 H331
Hazardous to the aquatic environment — Chronic Hazard, Category 1 H410

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS06



GHS09

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H301 - Toxic if swallowed
H331 - Toxic if inhaled
H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (CLP)

: P260 - Do not breathe dust
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P273 - Avoid release to the environment
P301+P310 - IF SWALLOWED: immediately call a POISON CENTER or doctor/physician

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Xylometazoline hydrochloride	(CAS No) 1218-35-5 (EC No) 214-936-4	99 - 101	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Inhalation), H331 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove victim to fresh air. Seek medical attention immediately. If not breathing, give artificial respiration.

- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical advice.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Seek medical advice.
- First-aid measures after ingestion : Rinse mouth. Drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention immediately.

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

- Symptoms/injuries : Blurred vision. Dizziness. May produce irregular heart beat and nervous symptoms.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

- Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : This product is flammable. On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides. Hydrochloric acid fumes.
- Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : 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

6.1.1. For non-emergency personnel

- Emergency procedures : Ensure adequate air ventilation. Avoid raising dust. Evacuate area.

6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment. Wear respiratory protection.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from sunlight.

Maximum storage period : 5 year

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dust production: dust mask with filter type P2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Crystalline powder.

Molecular mass : 280.8 g/mol

Colour : White.

Odour : odourless.

Odour threshold : No data available

pH : 5 - 6.6 25°C

pH solution : 100 g/l

Relative evaporation rate (butylacetate=1) : No data available

Melting point : 131 - 133 °C

Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Flammability (solid, gas) : No data available

Vapour pressure : No data available

Relative vapour density at 20 °C : No data available

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Relative density : No data available
Density : 600 kg/m³ 20°C
Solubility : Soluble in water.

Log Pow : 2.84
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available

Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Light (daylight).

10.5. Incompatible materials

Strong oxidizers. Strong acids. Bases.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Nitrogen oxides. Hydrochloric acid fumes.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Toxic if swallowed. Inhalation: Toxic if inhaled.

Xylometazoline hydrochloride (1218-35-5)	
LD50 oral rat	122 mg/kg
LC50 inhalation rat	0.47 - 1.08 mg/l 4 h

Skin corrosion/irritation : Not classified
pH: 5 - 6.6 25°C

Serious eye damage/irritation : Not classified
pH: 5 - 6.6 25°C

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

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STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Xylometazoline hydrochloride (1218-35-5)	
LC50 fish 1	71 mg/l Brachydanio rerio, 96 h
EC50 Daphnia 1	5.63 mg/l 48 h

12.2. Persistence and degradability

Xylometazoline hydrochloride (1218-35-5)	
Persistence and degradability	Minimally biodegradable.
Biodegradation	< 10 % 28 d

12.3. Bioaccumulative potential

Xylometazoline hydrochloride (1218-35-5)	
Log Pow	2.84

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment. Notify authorities if product enters sewers or public waters.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
6.1	6.1
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available	

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14.6. Special precautions for user

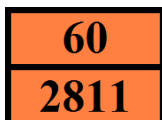
- Overland transport

Classification code (ADR) : T2

Excepted quantities (ADR) : E1

Hazard identification number (Kemler No.) : 60

Orange plates :



Tunnel restriction code (ADR) : E

EAC code : 2X

- Air transport

No data available

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Xylometazoline hydrochloride is not on the REACH Candidate List

Xylometazoline hydrochloride is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

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.

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods

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IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Full text of H- and EUH-statements:

Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
H301	Toxic if swallowed
H331	Toxic if inhaled
H410	Very toxic to aquatic life with long lasting effects

SDS EU (REACH Annex II) Version 2017

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