

Pseudoephedrine hydrochloride

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 29/03/2012 Revision date: 17/05/2017

648159

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Pseudoephedrine hydrochloride
IUPAC name : (1S,2S)-2-(Methylamino)-1-phenylpropan-1-ol hydrochloride
EC-No. : 206-462-1
CAS-No. : 345-78-8
Product code : 648159
Formula : C10H16ClNO
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 - The Netherlands
T +31(0)23-5319093
farma@duchefa.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 4 H302
Skin sensitisation, category 1B H317
Specific target organ toxicity — Single exposure, Category 3,
Respiratory tract irritation H335

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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) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H302 - Harmful if swallowed
H317 - May cause an allergic skin reaction
H335 - May cause respiratory irritation

Precautionary statements (CLP) :

P261 - Avoid breathing dust
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing

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]
Pseudoephedrine hydrochloride	(CAS-No.) 345-78-8 (EC-No.) 206-462-1	99 - 101	Acute Tox. 4 (Oral), H302 Skin Sens. 1B, H317 STOT SE 3, H335

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. If not breathing, give artificial respiration. Seek medical advice.

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 attention if ill effect or irritation develops.

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- First-aid measures after eye contact : Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
- First-aid measures after ingestion : Rinse mouth. Induce vomiting if person is conscious. Seek medical advice.

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

- Symptoms/effects : Exposure may produce an allergic reaction. Bitter taste. Headache. Dizziness. Nausea. Vomiting. May produce irregular heart beat and nervous symptoms. Weakness. Breathing difficulties.

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

- On ingestion : Give activated charcoal.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Carbon dioxide. Dry powder. Foam. Water spray.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Carbon dioxide. Nitrogen oxides. Hydrochloric acid fumes.
- Explosion hazard : Large amounts: Risk of dust explosion.

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.

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. Detergent.

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.

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7.2. Conditions for safe storage, including any incompatibilities

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

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

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace

Respiratory protection:

Dust production: dust mask with filter type P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 201.7 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 4.6 - 6
pH solution	: 5 % in H ₂ O
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: ca. 184 °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
Solubility	: Soluble in water. Soluble in ethanol.
Log Pow	: -2.19
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). heat.

10.5. Incompatible materials

Strong oxidizers.

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: Harmful if swallowed.

Pseudoephedrine hydrochloride (345-78-8)	
LD50 oral rat	1000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat	> 2000 mg/l/4h

Skin corrosion/irritation	: Not classified pH: 4.6 - 6
Serious eye damage/irritation	: Not classified pH: 4.6 - 6
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified

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STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Pseudoephedrine hydrochloride (345-78-8)	
LC50 fish 1	460 - 1000 mg/l 96 h
EC50 Daphnia 1	58.7 mg/l 48 h

12.2. Persistence and degradability

Pseudoephedrine hydrochloride (345-78-8)	
Persistence and degradability	Biodegradable.
Biodegradation	90 - 100 %

12.3. Bioaccumulative potential

Pseudoephedrine hydrochloride (345-78-8)	
Log Pow	-2.19

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.

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	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

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14.6. Special precautions for user

- Overland transport

No data available

- 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

Pseudoephedrine hydrochloride is not on the REACH Candidate List

Pseudoephedrine 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:

1.4	Emergency telephone	Modified	Added additional information
2	R-phrases	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Skin and body protection	Modified	Added additional information (type of clothing related to concentration levels)

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Skin Sens. 1B	Skin sensitisation, category 1B
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H335	May cause respiratory irritation

SDS EU (REACH Annex II) Version 2017

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