

Phenylephrine Hydrochloride

Safety Data Sheet

258407

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Date of issue: 20/03/2013 Revision date 10/03/2020
 Supersedes 15/02/2017

Version: 2.1

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

1.1. Product identifier

Product form : Substance
 Substance name : Phenylephrine Hydrochloride
 EC-No. : 200-517-3
 CAS-No. : 61-76-7
 Product code : 258407
 Formula : C₉H₁₃NO₂.HCL
 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 industry
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

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)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

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 corrosion/irritation, Category 2 H315
 Serious eye damage/eye irritation, Category 2 H319

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Specific target organ toxicity — Single exposure, Category 3, H335
Respiratory tract irritation


Full text of 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] Extra labelling to display
classification(s) to display

Hazard pictograms (CLP) : 
GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

Precautionary statements (CLP) : P261 - Avoid breathing dust, fume, gas, mist, vapours, spray.
P280 - Wear eye protection, face protection, protective clothing, protective gloves.
P301+P312 - IF SWALLOWED: Call a POISON CENTER, a doctor if you feel unwell.
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Pharmaceuticals

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Phenylephrine Hydrochloride	(CAS-No.) 61-76-7 (EC-No.) 200-517-3	100	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 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 general	: Call a physician. If possible show this sheet, if not available show packaging or label.
First-aid measures after inhalation	: Allow affected person to breathe fresh air If not breathing, give artificial respiration Call a POISON CENTER/doctor.
First-aid measures after skin contact	: Wash with plenty of water/... Get medical advice/attention.
First-aid measures after eye contact	: Immediately flush eyes thoroughly with water for at least 15 minutes Seek medical advice.
First-aid measures after ingestion	: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. dry chemical powder, alcohol-resistant foam, carbon dioxide (CO ₂).
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Carbon dioxide. Carbon monoxide. Nitrogen oxides. Hydrogen chloride gas.
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5.3. Advice for firefighters

Precautionary measures fire	: [In case of inadequate ventilation] wear respiratory protection.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid raising dust. Do not breathe dust. Ensure adequate ventilation. Evacuate area.
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6.1.1. For non-emergency personnel

Protective equipment	: Wear recommended personal protective equipment.
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6.1.2. For emergency responders

No additional information available

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6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

For containment : Avoid raising dust.

Methods for cleaning up : Sweep up dry powder and dispose properly.

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 : Avoid raising dust and aerosols. Do not get in eyes, on skin, or on clothing. Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, cool, well-ventilated area.

Storage temperature : 15 - 25 °C

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**Appropriate engineering controls:**

Handle in accordance with good industrial hygiene and safety practice.

Hand protection:

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

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

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 P2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Molecular mass	: 203.7 g/mol
Colour	:
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 143 - 145 °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
Relative density	: No data available
Solubility	: Soluble in ethanol Soluble in water.
Log Pow	: No data available
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

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

acids

Acid anhydrides

Oxidizing agent

Acid chlorides.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Harmful if swallowed.

Phenylephrine Hydrochloride (61-76-7)	
LD50 oral rat	350 mg/kg

Skin corrosion/irritation : Causes skin irritation.

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

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**

Regional legislation (waste) : Disposal must be done according to official regulations.

Waste treatment methods : Toxic and corrosive gases formed during combustion should be scrubbed before discharge to atmosphere.

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	

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

Phenylephrine Hydrochloride is not on the REACH Candidate List

Phenylephrine Hydrochloride is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

	Version	Modified	change of logo
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Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

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REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
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

Data sources : Supplier.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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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.