

# MATERIAL SAFETY DATA SHEET

Version No: MSDS/Phenylephrine-AUS/DP-001

Effective Date: 19<sup>th</sup> December 2020

## Phenylephrine hydrochloride Injection, 10 mg/mL, 1 mL

### SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Phenylephrine hydrochloride Injection, 10 mg/mL, 1 mL

<b>Intended Use:</b>	Finished medicinal product
<b>Details of the Supplier of the Safety Data Sheet</b>	
<b>Manufacturer:</b> Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India	<b>Sponsor:</b> Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia

### SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

#### Mixtures

#### Chemical characterization

**Adrenergic receptor agonist** :

**Active substance** : phenylephrine hydrochloride /3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol hydrochloride (1:1).

**Sum formula** : C<sub>9</sub>H<sub>13</sub>NO<sub>2</sub>.HCl

**Molecular weight** : 167,21 g/mol

#### Hazardous components:

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
200-517-3	phenylephrine hydrochloride / 3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol hydrochloride (1:1)	1 %
61-76-7	Xn - Harmful R22-43	
	Acute Tox. 4, Skin Sens. 1B, Aquatic Acute 2; H302 H317 H401	
01-2120047675-50		

**For the full text of R-, H- and EUH-phrases, see Section 16**

### SECTION 3 - HAZARDS IDENTIFICATION

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## Classification of the substance or mixture

**Indications of danger** : Xi - Irritant.

**R phrases** : May cause sensitisation by skin contact.

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

### Hazard categories:

**Respiratory/skin sensitization** : Skin Sens. 1B

**Hazard Statements** : May cause an allergic skin reaction

## Label elements

### Hazardous components which must be listed on the label

phenylephrine hydrochloride / 3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol hydrochloride (1:1)

**Signal word:** : Warning

**Pictograms** : GHS07



## Hazard statements

**H317** : May cause an allergic skin reaction.

## Precautionary statements

**P261** : Avoid breathing dust/fume/gas/mist/vapours/spray.

**P280** : Wear protective gloves/protective clothing/eye protection/face protection

**P302+P352** : IF ON SKIN: Wash with plenty of water

**P333+P313** : If skin irritation or rash occurs: Get medical advice/attention.

**P362+P364** : If skin irritation or rash occurs: Get medical advice/attention.

## Additional advice on labelling

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

**Other hazards** : Not known.

## SECTION 4 - FIRST AID MEASURES

**General information** : Remove contaminated soaked clothing immediately and dispose of safely. Take away from danger area and lay down affected person. If you feel unwell, seek medical advice.

**After inhalation** : In case of inhalation of mist seek medical advice. Information on label instructions. Remove the casualty into fresh air and keep him immobile. Medical treatment.

**After contact with** : Wash off immediately with soap and plenty of water. Consult a

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**skin** doctor if skin irritation persists.  
**After contact with eyes** : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.  
**After ingestion** : If swallowed, seek medical advice immediately and show this container or label. Rinse out mouth and give plenty of water to drink. Do not induce vomiting. Never give anything by mouth to an unconscious person.

## Most important symptoms and effects, both acute and delayed

Adrenergic receptor agonist

## Indication of any immediate medical attention and special treatment needed

Treat symptoms.

## SECTION 5 - FIRE FIGHTING MEASURES

### Extinguishing Media

**Suitable extinguishing media** : Product does not burn, fire-extinguishing activities according to surrounding. Alcohol-resistant foam, dry chemical, carbon dioxide (CO<sub>2</sub>), water-spray.

**Unsuitable extinguishing media** : Full water jet.

### Special hazards arising from the substance or mixture

In case of fire formation of dangerous gases possible

**Fire may produce** : Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>).

**Advice for firefighters** : Wear self-contained breathing apparatus and protective suit.

**Additional information** : Cool containers at risk with water spray jet. Collect contaminated firefighting water separately, must not be discharged into the drains. Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:** Get unprotected persons to safety. Do not breathe vapours. Use personal protective clothing. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Keep away sources of ignition.

**Environmental precautions:** Do not discharge into the drains/surface waters/ground water.

**Methods and material for containment and cleaning up:** Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder). Contaminated objects and floor

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clean thoroughly by consideration of environment regulations. Wear complete protection equipment (P3-mask, safety goggles, protective gloves) when cleaning the area.

**Reference to other sections:** Observe protective instructions (see Sections 7 and 8). Information for disposal see section 13.

## SECTION 7 - HANDLING AND STORAGE

### Precautions for safe handling

- Advice on safe handling** : Avoid formation of aerosols. Allow for sucking off. Handle and open container with care.  
Use personal protective clothing.
- Advice on protection against fire and explosion** : No specific precautions required.
- Further information on handling** : Take the usual precautions when handling with chemicals. At work do not eat, drink and smoke.

### Conditions for safe storage, including any incompatibilities

- Requirements for storage rooms and vessels** : Keep only in original container. Keep container tightly closed in a dry, cool and well-ventilated place. Store in a cool and shaded area.
- Advice on storage compatibility** : Do not store together with oxidizing agents. Do not store with acids or alkalies. Keep away from food, drink and animal feeding stuffs.
- Further information on storage conditions** : Protect against direct sun radiation. Keep away from heat.
- Specific end use(s)** : Finished medicinal product 8

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

- Additional advice on limit values** : Avoid exposure - before application obtain special instructions. Handling should only be allowed by trained Personnel.

### Exposure controls

- Appropriate engineering controls** : Ensure adequate ventilation, especially in confined areas. Avoid formation of Aerosols.  
Provide emergency shower.  
Provide eye bath.
- Protective and hygiene measures** : Wash hands before breaks and immediately after handling the product. When using do not eat, drink or smoke. Avoid contact with skin, eyes and clothing. Take off immediately all contaminated clothing.
- Eye/face protection** : Tightly fitting goggles (EN 166).

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- Hand protection** : Chemical-resistant gloves (EN 374). (Latex gloves.)  
Follow the recommendations of the glove manufacturer for breakthrough properties especially for workplace conditions involving mechanical stress and contact duration.
- Skin protection** : Protective suit.
- Respiratory protection** : No special protection is necessary when the product is handled inside a safety cabinet or an isolator. Not required; except in case of aerosol formation. Short term: filter apparatus, Filter P3

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

- Physical State** : Liquid
- Colour** : colorless, Clear
- pH-Value** : n.d.
- Initial boiling point and boiling range** : n.d.
- Flash point** : n.d.
- Vapour pressure (at 20 °C)** : n.d.
- Density (at 20 °C)** : n.d.
- Water solubility (at 20 °C)** : Soluble
- Other information** : No data available.

## SECTION 10 - STABILITY AND REACTIVITY

- Reactivity** : No decomposition if stored and applied as directed.
- Chemical stability** : Stable under normal conditions.
- Possibility of hazardous reactions** : Stable under normal conditions.
- Conditions to avoid** : To avoid thermal decomposition, do not overheat.
- Incompatible materials** : Not known.
- Hazardous decomposition products** : No decomposition if stored and applied as directed.

## SECTION 11 - TOXICOLOGY INFORMATION

### Information on toxicological effects

- Acute toxicity** : Based on available data, the classification criteria are not met.

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<b>Irritation and corrosivity</b>	: Based on available data, the classification criteria are not met.
<b>Sensitising effects</b>	: May cause an allergic skin reaction. (phenylephrine hydrochloride / 3-[(1R)-1-hydroxy-2 (methylamino)ethyl]phenol hydrochloride (1:1))
<b>STOT-single exposure</b>	: Based on available data, the classification criteria are not met.
<b>Severe effects after repeated or prolonged exposure</b>	: Based on available data, the classification criteria are not met.
<b>Carcinogenic/mutagenic/toxic effects for reproduction</b>	: Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	: Based on available data, the classification criteria are not met.
<b>Additional information on tests</b>	: Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

## SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

<b>Toxicity</b>	: No information available.
<b>Persistence and degradability</b>	: No information available.
<b>Bioaccumulative potential</b>	: No information available.
<b>Mobility in soil</b>	: No information available.
<b>Results of PBT and vPvB assessment</b>	: No information available.
<b>Other adverse effects</b>	: No information available
<b>Further information</b>	: Do not discharge into the drains/surface waters/ground water.

## SECTION 13 - DISPOSAL INFORMATION

### Waste Treatment Methods:

#### Advice on disposal

Waste disposal according to local regulations. Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

#### Waste disposal number of waste from residues/unused products

180108 : WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or

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prevention of disease in humans; cytotoxic and cytostatic medicines Classified as hazardous waste.

## Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.

## SECTION 14 - TRANSPORTATION INFORMATION

### Land transport (ADR/RID); Marine transport (IMDG); Air transport (ICAO); Inland waterways transport (ADN)

- UN number:** : Not applicable. No hazardous material as defined by the transport regulations.
- UN proper shipping name** : Not applicable. No hazardous material as defined by the transport regulations.
- Transport hazard class(es)** : Not applicable. No hazardous material as defined by the transport regulations.
- Packing group** : Not applicable. No hazardous material as defined by the transport regulations.
- Environmental hazards** : Not applicable. No hazardous material as defined by the transport regulations.
- Special precautions for user** : Not applicable. No hazardous material as defined by the transport regulations.
- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** : Not applicable. No hazardous material as defined by the transport regulations.

## SECTION 15 - REGULATORY INFORMATION

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

#### EU regulatory information

**Additional information** : According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

#### National regulatory information

**Employment restrictions** : Observe employment restrictions for young people. Observe employment restrictions for child bearing mothers and nursing.

**Chemical safety** : Chemical safety assessments for substances in this mixture

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assessment were not carried out.

## SECTION 16 - OTHER DATA

### Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

IMDG = International Maritime Code for Dangerous Goods

IATA/ICAO = International Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH = Registration, Evaluation, Authorization and Restriction of Chemicals

CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization

DIN = Deutsche Industrie Norm

PBT = Persistent Bioaccumulative and Toxic

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

### Relevant R-phrases (Number and full text)

22 : Harmful if swallowed.

43 : May cause sensitisation by skin contact.

### Relevant H- and EUH-phrases (Number and full text)

H302 : Harmful if swallowed.

H317 : May cause sensitisation by skin contact.

H401 Toxic to aquatic life.

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients.

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