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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

#### PETHIDINE SOLUTION

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD      Emergency Telephone +44 (0) 1235 239 670  
PO Box 131  
66 Talavera Rd, North Ryde  
NSW 2113  
AUSTRALIA  
+61 2 9978 3500  
  
SafetyDataSheets.AlderleyPark@astrazeneca.com

#### Alternative Names

Pethidine solution for injection  
Pethidine injection  
CAS No. : Not applicable

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

Use of the Substance/Mixture : opioid analgesic

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## SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Reproductive toxicity : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361 Suspected of damaging fertility or the unborn child.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P281 Use personal protective equipment as required.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/attention.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

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Pethidine hydrochloride

### Other hazards which do not result in classification

May cause vomiting, sedation and subdued behaviour

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Hazardous components

| Chemical name           | CAS-No. | Concentration (% w/w) |
|-------------------------|---------|-----------------------|
| Pethidine hydrochloride | 50-13-5 | 5                     |

## SECTION 4. FIRST AID MEASURES

- If inhaled : Remove patient from exposure.  
Obtain medical attention if ill effects occur.
- In case of skin contact : Wash skin with soap and water.
- In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes.  
Obtain medical attention if ill effects remain.
- If swallowed : Wash out mouth with water and give 200-300ml of water to drink.  
Obtain medical attention if ill effects occur.  
Do NOT induce vomiting as a First-Aid measure.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11  
Suspected of damaging fertility or the unborn child.
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.  
For further information consult the prescribing information.

## SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry powder or CO2.
- Unsuitable extinguishing media : -
- Specific hazards during firefighting : If involved in a fire, it may emit noxious and toxic fumes.
- Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and : Ensure suitable personal protection during removal of spillages.

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emergency procedures : See Section 8.

Environmental precautions : Prevent entry into drains, sewers or watercourses.

Methods and materials for containment and cleaning up : Clear up spillages.  
Transfer to a container for disposal.  
Wash the spillage area with water.

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## SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Avoid contact with skin and eyes.

Conditions for safe storage : Keep in a cool place.  
Protect from light.

Recommended storage temperature : < 25 °C

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## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.

### Personal protective equipment

Respiratory protection : Use an air fed hood if the risk assessment does not support the selection of other protection.

Eye protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

Skin and body protection : Use impervious clothing to protect against direct contact with the liquid or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for

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selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

|  |   |                   |
|--|---|-------------------|
| Appearance                                       | : | liquid            |
| Colour   | : | No data available |
| Odour  | : | No data available |
| Odour Threshold                                  | : | No data available |
| pH   | : | 3.5 - 6           |
| Melting point/range                              | : | No data available |
| Boiling point/boiling range                      | : | No data available |
| Flash point                                      | : | No data available |
| Evaporation rate                                 | : | No data available |
| Flammability (solid, gas)                        | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure                                  | : | No data available |
| Relative vapour density                          | : | No data available |
| Relative density                                 | : | No data available |
| Solubility(ies)                                  |   |                   |
| Water solubility                                 | : | No data available |
| Solubility in other solvents                     | : | No data available |
| Partition coefficient: n-octanol/water           | : | No data available |
| Auto-ignition temperature                        | : | No data available |
| Decomposition temperature                        | : | No data available |

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Viscosity  
  Viscosity, dynamic           : No data available  
  Viscosity, kinematic       : No data available  
Explosive properties         : No data available  
Oxidizing properties         : No data available

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity                    : No known reactivity hazard under normal conditions.  
Chemical stability           : Stable under normal conditions.  
Possibility of hazardous reactions   : None known.  
Conditions to avoid         : No conditions producing hazardous situations known.  
Incompatible materials      : None known.  
Hazardous decomposition products   : No hazardous decomposition products are known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1 Acute toxicity

Not classified based on available information.

#### **Product:**

Acute oral toxicity           : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

#### **Components:**

##### **Pethidine hydrochloride:**

Acute oral toxicity           : LD50 Oral (Rat): 170 mg/kg  
Remarks: May cause vomiting, sedation and subdued behaviour  
Ingestion may cause dryness of the mouth, thirst, difficulty in swallowing and acute effects in the eyes and on the cardiovascular system. High doses may produce muscle weakness, difficulty in breathing and unconsciousness.  
Acute inhalation toxicity    : Remarks: Adverse effects similar to ingestion may occur. May cause effects as described under single exposure.(STOT)  
Acute dermal toxicity         : Remarks: No information available.

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## 11.2 Skin corrosion/irritation

Not classified based on available information.

### Components:

#### **Pethidine hydrochloride:**

Remarks: May cause skin irritation.

## 11.3 Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### **Pethidine hydrochloride:**

Remarks: May cause eye irritation.

## 11.4 Respiratory or skin sensitisation

### **Skin sensitisation**

Not classified based on available information.

### **Respiratory sensitisation**

Not classified based on available information.

### Components:

#### **Pethidine hydrochloride:**

Remarks: No information available.

## Chronic toxicity

### 11.5 Germ cell mutagenicity

Not classified based on available information.

### Components:

#### **Pethidine hydrochloride:**

Germ cell mutagenicity - Assessment : The substance is not considered to be genotoxic.

### 11.6 Carcinogenicity

Not classified based on available information.

### Components:

#### **Pethidine hydrochloride:**

Carcinogenicity - Assessment : Inadequate information available to assess carcinogenic hazard.

### 11.7 Reproductive toxicity

Suspected of damaging fertility or the unborn child.

### Components:

#### **Pethidine hydrochloride:**

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Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments., Studies in animals have shown that high doses produce embryo/foetotoxic effects.

## 11.8 STOT - single exposure

Not classified based on available information.

### Components:

#### **Pethidine hydrochloride:**

Exposure routes: Inhalation

Target Organs: respiratory system

Remarks: May cause irritation to the respiratory system.

## 11.9 STOT - repeated exposure

Not classified based on available information.

### Components:

#### **Pethidine hydrochloride:**

Remarks: May cause effects as described under single exposure.(STOT)

## 11.10 Aspiration toxicity

Not classified based on available information.

### Components:

#### **Pethidine hydrochloride:**

No information available.

### **Further information**

#### Product:

Remarks: This health hazard assessment is based on a consideration of the composition of this product.

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## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### Product:

Toxicity to fish

:

Remarks: No information available.

#### Components:

#### **Pethidine hydrochloride:**

Toxicity to fish

:

Remarks: No information available.

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## Persistence and degradability

### Components:

#### Pethidine hydrochloride:

Biodegradability : Remarks: No degradation data available. The substance is assumed not to be rapidly degradable.

## Bioaccumulative potential

### Components:

#### Pethidine hydrochloride:

Bioaccumulation : Remarks: No information available.

## Mobility in soil

### Components:

#### Pethidine hydrochloride:

Mobility : Remarks: No information available.

Distribution among environmental compartments : Remarks: No information available.

## Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Disposal should be in accordance with local, state or national legislation.  
This material and/or its container must be disposed of as hazardous waste.  
Dispose of contents/ container to an approved incineration plant.

Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.

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## SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.



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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

In order to comply with legal duties it is necessary to consult local and national legislation.

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

**The components of this product are reported in the following inventories:**

REACH : Not listed

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Pethidine hydrochloride 50-13-5

AICS : Not listed

ENCS : Not listed

ISHL : Not listed

IECSC : Not listed

TCSI : Not listed

TSCA : Not On TSCA Inventory

**SECTION 16. OTHER INFORMATION****Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety

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and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

## Further information

|                   |   |  |
|-------------------|---|--|
| Revision Date     | : | 18.01.2018   |
| Other information | : | The Safety Data Sheet has been updated to the SAP EH&S Standard template., This update affects all Sections of the Safety Data Sheet., New significant SHE information:, 2. New classification |
| Date format       | : | dd.mm.yyyy   |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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