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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

## FENTANYL SOLUTION FOR INJECTION

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

### Alternative Names

Fentanyl 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

Not a hazardous substance or mixture.

### GHS label elements

Not a hazardous substance or mixture.

### Other hazards which do not result in classification

Can be absorbed through skin causing systemic toxic effects.

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## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Fentanyl citrate	990-73-8	< 0.1

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## SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure.  
Obtain medical attention if ill effects occur.

In case of skin contact : Remove contaminated clothing.  
Wash skin with water.  
If symptoms (irritation or blistering) occur obtain medical attention.

In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes.  
Obtain medical attention.

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- If swallowed : Wash out mouth with water and give 200-300ml of water to drink.  
Do NOT induce vomiting as a First-Aid measure.  
Obtain medical attention.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.  
For further detail consult the prescribing information.
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## SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry powder or CO<sub>2</sub>.
- 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.
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## SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.  
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 container tightly closed.  
Protect from light.  
Do not freeze.
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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

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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 appropriate respiratory protective equipment.
- Eye protection : Wear appropriate eye protection.
- Skin and body protection : Wear appropriate protective clothing and gloves.
- 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 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.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

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#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : aqueous solution
- Colour : clear, colourless
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/range : No data available
- Initial boiling point and boiling range : No data available
- Flash point : No data available

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Evaporation rate : No data available

Flammability (solid, gas) : No data available

Upper explosion limit : No data available

Lower explosion 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

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

### 11.1.1 Acute toxicity

Not classified based on available information.

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**Product:**

Acute oral toxicity : Remarks: Low acute oral toxicity.  
Acute inhalation toxicity : Remarks: May cause effects as described under single exposure.(STOT)

**Components:****Fentanyl citrate:**

Acute oral toxicity : LD50 (Rat): 18 mg/kg  
Remarks: Fatal if swallowed.  
Acute inhalation toxicity : Remarks: Inhalation may produce toxic effects.  
Acute dermal toxicity : Remarks: Can be absorbed through skin causing systemic toxic effects.

**11.1.2 Skin corrosion/irritation**

Not classified based on available information.

**Components:****Fentanyl citrate:**

Remarks: Contact dermatitis has been reported with related compounds.

**11.1.3 Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Fentanyl citrate:**

Remarks: May cause mild eye irritation.

**11.1.4 Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Fentanyl citrate:**

Remarks: Unlikely to cause skin sensitisation.

**11.1.5 Germ cell mutagenicity**

Not classified based on available information.

**Components:****Fentanyl citrate:**

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

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## 11.1.6 Carcinogenicity

Not classified based on available information.

### Components:

#### **Fentanyl citrate:**

Carcinogenicity -                                : No information available.  
Assessment

## 11.1.7 Reproductive toxicity

Not classified based on available information.

### Components:

#### **Fentanyl citrate:**

Reproductive toxicity -                        : Effects on or via lactation  
Assessment

## 11.1.8 STOT - single exposure

Not classified based on available information.

### Components:

#### **Fentanyl citrate:**

Exposure routes: Oral, Inhalation

Remarks: May cause vomiting, sedation and subdued behaviour

May cause difficulty in breathing, muscle spasm, cardiovascular effects and unconsciousness.

May cause pupil contraction.

Exposure routes: Inhalation

Assessment: May cause drowsiness or dizziness.

## 11.1.9 STOT - repeated exposure

Not classified based on available information.

### Components:

#### **Fentanyl citrate:**

Exposure routes: Inhalation

Target Organs: Lungs, Central nervous system

Remarks: Repeated exposure to dust may cause CNS-depression and changes in lung function

## 11.1.10 Aspiration toxicity

Not classified based on available information.

### Components:

#### **Fentanyl citrate:**

No information available.

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## 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:

#### Ecotoxicology Assessment

Chronic aquatic toxicity : This product has no known ecotoxicological effects.  
Remarks: The following information refers to Fentanyl hydrochloride

#### Components:

##### Fentanyl citrate:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 12.3 mg/l  
Exposure time: 48 H  
Method: OECD Test Guideline 202

Remarks: Information refers to Fentanyl hydrochloride

### Persistence and degradability

#### Components:

##### Fentanyl citrate:

Biodegradability : Result: not rapidly degradable

### Bioaccumulative potential

#### Components:

##### Fentanyl citrate:

Bioaccumulation : Remarks: The substance has potential for bioaccumulation.

### Mobility in soil

#### Components:

##### Fentanyl citrate:

Mobility : Remarks: No information available.

Distribution among environmental compartments : Remarks: No information available.

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**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.
- 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.

- 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.
- Fentanyl citrate 990-73-8
- AICS : On the inventory, or in compliance with the inventory
- ENCS : Not listed
- ISHL : Not listed
- IECSC : Not listed
- TCSI : Not listed
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TSCA : Not On TSCA Inventory

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## 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; COM - In-house occupational exposure limit; CPR - Controlled Products Regulations; 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; HYG - Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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 and Health Law (Japan); ISO - International Organisation for Standardization; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); 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; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (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; Sen - Capable of causing respiratory sensitization; Sk - Can be absorbed through skin, thus contributing to systemic effects; STEL - Short-term exposure limit 15-minutes time-weighted average; TLV - Threshold Limit Value (ACGIH); TLV-C - Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA - Long-term exposure limit 8h time-weighted average; 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

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., Minor changes:, 2, 6, 8, 13

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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