SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

BYETTA SOLUTION FOR INJECTION

Details of the supplier of the safety data sheet:
ASTRAZENECA PTY LTD
PO Box 131
Alma Road, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500
SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names
Exenatide solution for injection
Exenatide injection, 250 mcg/mL
CAS No.: Not applicable

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

Use of the Substance/Mixture: Treatment of Type II Diabetes

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
May cause skin and eye irritation.
See Section 11.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exenatide</td>
<td>141758-74-9</td>
<td>&lt; 0.1</td>
</tr>
</tbody>
</table>

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

Notes to physician: Symptomatic treatment and supportive therapy as indicated. For further detail 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: Low fire hazard.

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 emergency procedures: Ensure suitable personal protection during removal of spillages. Ensure adequate ventilation. See Section 8.

Environmental precautions: Prevent entry into drains.

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

SECTION 7. HANDLING AND STORAGE

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

Conditions for safe storage: Keep container tightly closed. Do not freeze. Protect from light.

Recommended storage temperature: 2 - 8 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis
--- | --- | --- | --- | ---
Exenatide | 141758-74-9 | TWA | 0.5 µg/m³ | COM

**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.

**Personal protective equipment**

**Respiratory protection**

If needed, use suitable respiratory 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

liquid

**Colour**

No data available

**Odour**

No data available

**Odour Threshold**

No data available

**pH**

3.5 - 5.5

**Melting point/range**

No data available
Initial boiling point and boiling range : No data available
Flash point : No data available
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) : No data available
  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 : No data available
  Viscosity, dynamic : No data available
  Viscosity, kinematic : No data available
Explosive properties : No data available
Oxidizing properties : No data available

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 : No hazardous decomposition products are known.
SECTION 11. TOXICOLOGICAL INFORMATION

11.1.1 Acute toxicity

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

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

Components:
Exenatide:
Acute oral toxicity : Remarks: No information available.
Acute inhalation toxicity : Remarks: May cause effects as described under repeated exposure.(STOT)
Acute dermal toxicity : Remarks: No information available.

11.1.2 Skin corrosion/irritation

Components:
Exenatide:
Remarks: No information available.

11.1.3 Serious eye damage/eye irritation

Components:
Exenatide:
Remarks: No information available.

11.1.4 Respiratory or skin sensitisation

Components:
Exenatide:
Remarks: No information available.

11.1.5 Germ cell mutagenicity

Components:
Exenatide:
Germ cell mutagenicity : There is no evidence of genotoxic potential in in vitro and in vivo tests.
11.1.6 Carcinogenicity

Components:

Exenatide:
Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies. Studies in animals have shown that repeated doses produce tumours in rats. The relevance to humans is unknown.

11.1.7 Reproductive toxicity

Components:

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

11.1.8 STOT - single exposure

Components:

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

11.1.9 STOT - repeated exposure

Components:

Exenatide:
Exposure routes: Inhalation, Oral
Remarks: May cause headache, nausea, vomiting, diarrhoea and nasopharyngitis.

11.1.10 Aspiration toxicity

Components:

Exenatide:
No information available.

Further information

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Exenatide:
Toxicity to fish: Remarks: No information available.

**Persistence and degradability**

**Components:**

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

**Bioaccumulative potential**

**Components:**

**Exenatide:**
Bioaccumulation: Remarks: No information available.

**Mobility in soil**

**Components:**

**Exenatide:**
Mobility: Remarks: No information available.

Distribution among environmental compartments: Remarks: No information available.

**Other adverse effects**
No data available

### 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.

### SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.
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.

Exenatide 141758-74-9

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; 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,
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.