

Version 3.0 Revision Date: 07.04.2020 SDS Number: 21170 Date of last issue: 22.08.2017
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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 Emergency Telephone
PO Box 131 +44 (0) 1235 239 670
66 Talavera Rd, 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

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
m-Cresol	108-39-4	0.1 -0.9
Exenatide	141758-74-9	0.025

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.

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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.

See section 13.

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

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
m-Cresol	108-39-4	TWA	5 ppm 22 mg/m ³	AU OEL
Further information: Skin absorption				
		TWA (Inhalable fraction and vapor)	20 mg/m ³	ACGIH
Exenatide	141758-74-9	TWA	0.5 µg/m ³	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

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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 / 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

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.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 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.

11.2 Skin corrosion/irritation

Components:

Exenatide:

Remarks : No information available.

11.3 Serious eye damage/eye irritation

Components:

Exenatide:

Remarks : No information available.

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11.4 Respiratory or skin sensitisation

Components:

Exenatide:

Remarks : No information available.

Chronic toxicity

11.5 Germ cell mutagenicity

Components:

Exenatide:

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

11.6 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.

11.7 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.

11.8 STOT - single exposure

Components:

Exenatide:

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

11.9 STOT - repeated exposure

Components:

Exenatide:

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

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11.10 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:

m-Cresol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 15.9 mg/l
Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): 8.9 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 8.9 mg/l
Exposure time: 24 h

Toxicity to algae/aquatic plants : EC0 (blue-green algae): 1 mg/l

EC100 (blue-green algae): 10 mg/l

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 1.35 mg/l
Exposure time: 32 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)):
Exposure time: 21 d

Toxicity to microorganisms : EC50 (Sewage sludge organisms): 461.4 mg/l
Exposure time: 3 h

Ecotoxicology Assessment

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Exenatide:

Toxicity to fish : Remarks: No information available.

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Persistence and degradability**Components:****m-Cresol:**

Biodegradability : Result: rapidly biodegradable
Biodegradation: > 90 %
Exposure time: 28 d

Exenatide:

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

Bioaccumulative potential**Components:****m-Cresol:**

Bioaccumulation : Species: Leuciscus idus (Golden orfe)
Bioconcentration factor (BCF): 20

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.

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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:

TCSI : Not listed

TSCA : Substance(s) not listed on TSCA inventory

AICS : Not listed

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

ENCS : Not listed

ISHL : Not listed

KECI : Not listed

IECSC : Not listed

CHINV : Not in compliance with the inventory

REACH : Not in compliance with the inventory

TRINV : Not in compliance with the inventory

SECTION 16. OTHER INFORMATION

Further information

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Other information : New significant SHE information:
8. New Occupational Exposure Limit Value
Minor changes:
3
6
15

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average
AU OEL / TWA : Exposure standard - time weighted average

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; CHINV - China Inventory; 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); TRINV - Turkey Inventory; 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

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

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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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