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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

BYDUREON MIXTURE 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	Emergency Telephone +44 (0) 1235 239 670
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SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

Exenatide mixture for suspension for injection
 Exenatide extended-release for injectable suspension
 Bydureon Control sample
 Exenatide once weekly
 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

Carcinogenicity : Category 2
 Reproductive toxicity : Category 2

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H351 Suspected of causing cancer.
 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:

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P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

See Section 11.

May form explosible dust-air mixture if dispersed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 10 - < 20
Exenatide	141758-74-9	>= 1 - < 10

SECTION 4. FIRST AID MEASURES

- If inhaled : Remove patient from exposure, keep warm and at rest. Obtain medical attention if ill effects occur.
- In case of skin contact : Take off all contaminated clothing immediately. After contact with skin, wash immediately with plenty of water. Obtain medical attention.
- In case of eye contact : Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
- 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 if ill effects occur.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
 Suspected of causing cancer.
 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 : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
- 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 full personal protection during removal of spillages. Avoid dispersal of dust in the air. See Section 8.
- Environmental precautions : Prevent entry into drains, sewers or watercourses.
- Methods and materials for containment and cleaning up : Moisten spillages with water. Transfer to a container for disposal. Wash the spillage area with water.

SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Do not breathe dust. Avoid contact with skin and eyes. See Section 8. Minimize dust generation and accumulation. The material may form explosible dust-air mixture if dispersed. Dust clouds may be extremely sensitive to ignition by electrostatic discharge and other ignition sources. Ensure good earthing of equipment and personnel.
- Conditions for safe storage : Keep container tightly closed. Protect from light. Do not freeze.
- Recommended storage temperature : 2 - 8 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m ³	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 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, sewers or watercourses.

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Personal protective equipment

- Respiratory protection : Use an air fed hood for occasional exposures or for repeated exposures use a self-contained breathing apparatus if the risk assessment does not support the selection of other protection.
- Eye protection : Use safety glasses to protect against direct contact with the substance 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 product or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.
- 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 : powder
- Colour : white to off-white
- 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

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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)

 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

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.

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

Not classified based on available information.

Components:

Exenatide:

Remarks: No information available.

11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Exenatide:

Remarks: No information available.

11.1.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Exenatide:

Remarks: No information available.

11.1.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Exenatide:

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

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11.1.6 Carcinogenicity

Suspected of causing cancer.

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

Suspected of damaging fertility or the unborn child.

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

Not classified based on available information.

Components:

Exenatide:

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

11.1.9 STOT - repeated exposure

Not classified based on available information.

Components:

Exenatide:

Exposure routes: Inhalation, Oral

Remarks: May cause headache, nausea, vomiting, diarrhoea and nasopharyngitis.

11.1.10 Aspiration toxicity

Not classified based on available information.

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.

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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.
Waste, even small quantities, should never be poured down drains, sewers or water courses.
Dispose of contents/ container to an approved incineration plant.
- Contaminated packaging : Empty container will retain residue. Observe all hazard precautions.

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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.

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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 -

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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, 3, 4, 6, 8, 11

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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