

Version 4.0 Revision Date: 30.11.2018 SDS Number: 1900 Date of last issue: 07.02.2018
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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

CASODEX TABLETS

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

Bicalutamide tablets

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 prostate cancer

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H351 Suspected of causing cancer.
H360 May damage fertility or the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P273 Avoid release to the environment.
P281 Use personal protective equipment as required.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/

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attention.
 P391 Collect spillage.

Disposal:

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

Other hazards which do not result in classification

May cause anti-androgenic effects.

The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Bicalutamide	90357-06-5	39
Celluloses	9004-34-6	1.9 -2
Magnesium stearate	557-04-0	1.2

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 causing cancer.
 May damage fertility or the unborn child.
- 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 : 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 burn and emit noxious and toxic fumes.

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Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
 Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.
 Avoid dispersal of dust in the air.
 See Section 8.

Environmental precautions : Prevent entry into drains.
 Collect spillage.

Methods and materials for containment and cleaning up : Avoid dust generation.
 Transfer spilled tablets to a suitable container for disposal.
 Wash the spillage area with water.
 Avoid release to the environment.

 See section 13.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Avoid contact with skin and eyes.
 Wash hands after use.
 Minimize dust generation and accumulation.
 The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

Conditions for safe storage : Keep container tightly closed.

Recommended storage temperature : < 30 °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
Bicalutamide	90357-06-5	TWA	0.01 mg/m ³	COM; HYG
Celluloses	9004-34-6	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
Magnesium stearate	557-04-0	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

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		(Inhalable fraction)		
		TWA (Respirable fraction)	3 mg/m3	ACGIH

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.
See Section 6 for environmental precautions.

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 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 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

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Appearance : coated tablets

Colour : 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 : Not applicable

Flash point : Not applicable

Evaporation rate : Not applicable

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 : Not applicable

Relative vapour density : Not applicable

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 : Not applicable

 Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : Not applicable

SECTION 10. STABILITY AND REACTIVITY

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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

Not classified based on available information.

Components:

Bicalutamide:

Acute oral toxicity	:	No evident toxicity in rats at a dose of: 2,000 mg/kg Assessment: The substance or mixture has no acute oral toxicity
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

Not classified based on available information.

Components:

Bicalutamide:

Remarks	:	Non-irritant in vivo. Unlikely to cause skin irritation.
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11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Bicalutamide:

Remarks	:	Non-irritant in vivo. Unlikely to cause eye irritation.
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11.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

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Respiratory sensitisation

Not classified based on available information.

Components:**Bicalutamide:**

Remarks : It is not a skin sensitiser in vivo.
Unlikely to cause skin sensitisation.

Chronic toxicity**11.5 Germ cell mutagenicity**

Not classified based on available information.

Components:**Bicalutamide:**

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

11.6 Carcinogenicity

Suspected of causing cancer.

Components:**Bicalutamide:**

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

11.7 Reproductive toxicity

May damage fertility or the unborn child.

Components:**Bicalutamide:**

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments., May cause anti-androgenic effects., In male rats reproductive performance was reduced but was reversible after cessation of dosing., Evidence of altered sexual development was observed in the male offspring.

11.8 STOT - single exposure

Not classified based on available information.

Components:**Bicalutamide:**

Remarks : No specific effects reported.

11.9 STOT - repeated exposure

Not classified based on available information.

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Components:**Bicalutamide:**

Remarks : May cause anti-androgenic effects, including breast swelling and pain, hot flushes and pruritus.

11.10 Aspiration toxicity

Not classified based on available information.

Components:**Bicalutamide:**

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Bicalutamide:**

<p>Toxicity to fish</p> <p>NOEC (Oncorhynchus mykiss (rainbow trout)): 7.1 mg/l Exposure time: 96 H</p> <p>LC50 (Lepomis macrochirus (Bluegill sunfish)): > 4.4 mg/l Exposure time: 96 H</p> <p>NOEC (Lepomis macrochirus (Bluegill sunfish)): 4.4 mg/l Exposure time: 96 H</p>	<p>: LC50 (Oncorhynchus mykiss (rainbow trout)): > 7.1 mg/l Exposure time: 96 H Test Type: static test</p>
<p>Toxicity to algae</p>	<p>: NOEC (green algae): 1.1 mg/l</p> <p>NOEC (blue-green algae): 1.1 mg/l</p>
<p>Toxicity to fish (Chronic toxicity)</p>	<p>: NOEC (Pimephales promelas (fathead minnow)): 0.01 mg/l Exposure time: 124 d Method: OECD Test Guideline 210</p>
<p>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</p>	<p>: NOEC (Daphnia magna (Water flea)): 0.56 mg/l Exposure time: 21 d</p>
<p>M-Factor (Chronic aquatic toxicity)</p>	<p>: 10</p>
<p>Toxicity to microorganisms</p>	<p>: EC50 (activated sludge): > 100 mg/l Exposure time: 3 H Remarks: There is no evidence of inhibition to the aerobic treatment process at a concentration of 100 mg/l.</p>

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Persistence and degradability**Components:****Bicalutamide:**

Biodegradability : aerobic
Concentration: 100 mg/l
Chemical oxygen demand
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Result: not rapidly degradable

Remarks: There is no evidence of hydrolysis in water.

Bioaccumulative potential**Components:****Bicalutamide:**

Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

Mobility in soil**Components:****Bicalutamide:**

Mobility : Remarks: The substance has moderate mobility in groundwater.
The substance has moderate mobility in soil.
Water solubility ≥ 1 mg/l.

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 product residue. Observe all hazard precautions.

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SECTION 14. TRANSPORT INFORMATION

ICAO/IATA

UN No. : 3077
Proper Shipping Name : Environmentally hazardous substance, solid, n.o.s. (BICALUTAMIDE)
Class : 9
Packing Group : III
Environmental hazards : Environmentally hazardous

IMO/IMDG

UN No. : 3077
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (BICALUTAMIDE)
Class : 9
Packing Group : III
Marine pollutant : Marine pollutant

ADR

UN No. : 3077
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (BICALUTAMIDE)
Class : 9
Label(s) : 9
Packing Group : III
Environmental hazards : Environmentally hazardous

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

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Commonwealth, State or Territory
legislation.

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

REACH : Not in compliance with the inventory

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

AICS : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

Further information

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Other information : New significant SHE information:
2. New classification
3. Composition/information on ingredients
8. New Occupational Exposure Limit Value
Minor changes:
2
9
11
12
15
16

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; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit;

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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

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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