

Version 3.0 Revision Date: 07.02.2018 SDS Number: 1900 Date of last issue: -
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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
Acute aquatic toxicity : Category 2
Chronic aquatic toxicity : 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.
H401 Toxic to aquatic life.
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.

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Response:

P308 + P313 IF exposed or concerned: Get medical advice/
 attention.
 P391 Collect spillage.

Disposal:

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

Hazardous components which must be listed on the label:

Bicalutamide

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

Hazardous components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--------------------|------------|-----------------------|
| Bicalutamide | 90357-06-5 | 39 |
| 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

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- 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.
- 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 |
| Magnesium stearate | 557-04-0 | TWA | 10 mg/m ³ | AU OEL |

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| | | | |
|--|--|----------|-------|
| | Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica | | |
| | TWA | 10 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

Appearance : coated tablets

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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 : 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

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 | : | Assessment: The substance or mixture has no acute oral toxicity Remarks: No evident toxicity in rats at a dose of 2000mg/kg. |
| 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: Unlikely to cause skin irritation.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Bicalutamide:

Remarks: Unlikely to cause eye irritation.

11.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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Components:**Bicalutamide:**

Remarks: 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, Studies in animals have shown that repeated doses produce cancer in rats and mice.

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.

Components:**Bicalutamide:**

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

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pruritus.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Bicalutamide:

No data available

Further information

Product:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

M-Factor (Chronic aquatic toxicity) : 1

Ecotoxicology Assessment

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Components:

Bicalutamide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 7.1 mg/l
Exposure time: 96 H
Test Type: static test

NOEC (Oncorhynchus mykiss (rainbow trout)): 7.1 mg/l
Exposure time: 96 H

LC50 (Lepomis macrochirus (Bluegill sunfish)): > 4.4 mg/l
Exposure time: 96 H
Test Type: static test

NOEC (Lepomis macrochirus (Bluegill sunfish)): 4.4 mg/l
Exposure time: 96 H

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): > 5.3 mg/l
Exposure time: 48 H

Toxicity to algae : EC50 (green algae): > 1.1 mg/l
Exposure time:
Test Type: growth rate

NOEC (green algae): 1.1 mg/l

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Exposure time: 14 d

NOEC (blue-green algae): 1.1 mg/l
Exposure time: 21 d

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.01 mg/l
Exposure time: 124 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.56 mg/l
Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50 (bacteria, anaerobic): > 100 mg/l

Remarks: (tested at concentration above water solubility)

EC50 (nitrifying bacteria): > 100 mg/l

Remarks: (tested at concentration above water solubility)

Remarks: There is no evidence of inhibition to the aerobic treatment process at a concentration of 100 mg/l.

Persistence and degradability

Components:

Bicalutamide:

Biodegradability : 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 \geq 1 mg/l.

Distribution among : Remarks: No information available.

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environmental compartments

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.
-

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

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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.

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.
Bicalutamide 90357-06-5
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; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; 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; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International

