Version	Revision Date:	SDS Number:	Date of last issue: -
5.0	07.02.2018	1900	Date of first issue: 07.02.2018

SECTION 1. IDENTIFICATION

1.1 Product identifier

CASODEX TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA
1004 Middlegate Road
Mississauga
Ontario L4Y 1M4
CANADA
+1 800 668 6000

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency telephone
+44 (0) 1235 239 670

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 in accordance with the Hazardous Products Regulations

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.
P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

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.

Other hazards

May cause anti-androgenic effects.
The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate and if it is dispersed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

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. FIRE-FIGHTING MEASURES

Suitable extinguishing media : water spray, foam, dry chemical or CO2.

Unsuitable extinguishing media	:	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
Specific hazards during fire fighting	:	If involved in a fire, it may burn and emit noxious and toxic fumes.
Special protective equipment for fire-fighters	:	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 and if it is dispersed.
Conditions for safe storage	:	Keep container tightly closed.
Recommended storage temperature	:	< 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Bicalutamide	90357-06-5	TWA	0.01 mg/m3	COM; HYG
Magnesium stearate	557-04-0	TWA	10 mg/m3	CA AB OEL
		TWA	10 mg/m3	CA BC OEL

		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 : As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment. Consult a qualified safety and health professional for additional guidance, as needed.

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

Color : white

Odor : No data available

Odor 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
Vapor pressure	:	No data available
Relative vapor 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
Autoignition 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.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1. Acute toxicity

Not classified based on available information.

Ingredients:

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.

Ingredients:

Bicalutamide:

Remarks: Unlikely to cause skin irritation.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:

Bicalutamide:

Remarks: Unlikely to cause eye irritation.

11.4 Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Ingredients:

Bicalutamide:

Remarks: Unlikely to cause skin sensitization.

11.5 Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Bicalutamide:

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

11.6 Carcinogenicity

Suspected of causing cancer.

Ingredients:

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.

Ingredients:

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.

Ingredients:

Bicalutamide:

Remarks: No specific effects reported.

11.9 STOT-repeated exposure

Not classified based on available information.

Ingredients:

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.

Ingredients:

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.

Ingredients:

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
Exposure time: 14 d

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

Toxicity to fish (Chronic : NOEC (Pimephales promelas (fathead minnow)): 0.01 mg/l

toxicity) 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 (mg/l) of 100.

Persistence and degradability

Ingredients:

Bicalutamide:

Biodegradability : Result: not rapidly degradable
Remarks: There is no evidence of hydrolysis in water.

Bioaccumulative potential

Ingredients:

Bicalutamide:

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

Mobility in soil

Ingredients:

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.

SECTION 14. TRANSPORT INFORMATION

This material is not regulated for domestic transportation within Canada when shipped in non-bulk packages by air, highway or rail.

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

DOT (Department of Transport)

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

SECTION 15. REGULATORY INFORMATION

The ingredients 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
AICS	:	Not listed
ENCS	:	Not listed
ISHL	:	Not listed
IECSC	:	Not listed
TCSI	:	Not listed
TSCA	:	Not On TSCA Inventory

Canadian lists

No substances are subject to a Significant New Activity Notification.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour 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; 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 Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; 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; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (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; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); 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 Safety Data Sheet has been updated to the SAP EH&S Standard template.
This update affects all Sections of the Safety Data Sheet.
New significant SHE information:
2. New classification
Minor changes:
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Revision Date : 07.02.2018

The information provided in this Material 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.

CA / Z2