

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.05.2019

Version number 1

Revision: 29.05.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Product name: Bicalutamide****Part number:** Cat 1115**CAS Number:**
90357-06-5**EC number:**
618-534-3**1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

Application of the substance / the mixture Reference material for laboratory use only**1.3 Details of the supplier of the safety data sheet****Manufacturer/Supplier:**British Pharmacopoeia Commission
MHRA
10 South Colonnade
Canary Wharf
London E14 4PU
United KingdomTel : +44 (0)20 3080 6561
eMail: bpcrs@mhra.gov.uk**Further information obtainable from:** eMail: bpcrs@mhra.gov.uk**1.4 Emergency telephone number:** +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

GHS08 health hazard

Repr. 1B

H360FD May damage fertility. May damage the unborn child.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008**

The substance is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS07



GHS08

Signal word Danger

(Contd. on page 2)

GB

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.05.2019

Version number 1

Revision: 29.05.2019

Product name: Bicalutamide

(Contd. from page 1)

· Hazard statements

- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H360FD May damage fertility. May damage the unborn child.
- H335 May cause respiratory irritation.
- H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P321 Specific treatment (see on this label).
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Additional information:

Restricted to professional users.

· 2.3 Other hazards**· Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients**· 3.1 Chemical characterisation: Substances****· CAS No. Description**

90357-06-5 Bicalutamide

· Identification number(s) None**· EC number: 618-534-3****· RTECS: TX1413500****· Additional information:** For the wording of the listed hazard phrases refer to section 16.**SECTION 4: First aid measures****· 4.1 Description of first aid measures****· After inhalation:** Supply fresh air; consult doctor in case of complaints.**· After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing: Rinse mouth. Do not induce vomiting.**· 4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.**· 4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

GB

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.05.2019

Version number 1

Revision: 29.05.2019

Product name: Bicalutamide

(Contd. from page 2)

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable for surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Avoid formation of dust.
- **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose of contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Store in cool, dry place in tightly closed receptacles.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
Store only in the original receptacle unless other advice is given on the CoA.
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** Lists used were valid at the time of SDS preparation.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.

(Contd. on page 4)

GB

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.05.2019

Version number 1

Revision: 29.05.2019

Product name: Bicalutamide

(Contd. from page 3)

*Immediately remove all soiled and contaminated clothing**Wash hands before breaks and at the end of work.**Avoid contact with the eyes and skin.***· Respiratory protection:***In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.***· Protection of hands:***The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.**Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation**The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374*

Protective gloves

· Material of gloves Fluorocarbon rubber (Viton)**· Penetration time of glove material***The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.***· Eye protection:**

Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties**· General Information****· Appearance:****Form:** Solid**Colour:** White**· Odour:** Odourless**· Odour threshold:** Not determined.**· pH-value:** Not applicable.**· Change in condition****Melting point/freezing point:** 191-195 °C**Initial boiling point and boiling range:** Not determined.**· Flash point:** Not applicable.**· Flammability (solid, gas):** Not determined.**· Ignition temperature:** Not determined**· Decomposition temperature:** Not determined.**· Auto-ignition temperature:** Not determined.

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 29.05.2019

Version number 1

Revision: 29.05.2019

Product name: Bicalutamide

(Contd. from page 4)

· Explosive properties:	<i>Not determined.</i>
· Explosion limits:	
Lower:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>
· Vapour pressure:	<i>Not applicable.</i>
· Density:	<i>Not determined.</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not applicable.</i>
· Evaporation rate	<i>Not applicable.</i>
· Solubility in / Miscibility with	<i>Freely soluble in tetrahydrofuran and in acetone; soluble in acetonitrile</i>
· water:	<i>Not determined.</i>
· Partition coefficient: n-octanol/water:	<i>1.738 log P</i>
· Viscosity:	
Dynamic:	<i>Not applicable.</i>
Kinematic:	<i>Not applicable.</i>
· 9.2 Other information	<i>No further relevant information available.</i>

SECTION 10: Stability and reactivity

· **10.1 Reactivity**

Stable under normal conditions.

No further relevant information available.

· **10.2 Chemical stability** *Stable under normal conditions.*

· **Thermal decomposition / conditions to be avoided:**

Formation of toxic gases is possible during heating or in case of fire.

· **10.3 Possibility of hazardous reactions** *No dangerous reactions known.*

· **10.4 Conditions to avoid** *Heat.*

· **10.5 Incompatible materials:** *Strong oxidizing agents.*

· **10.6 Hazardous decomposition products:**

Formation of toxic gases is possible during heating or in case of fire.

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**

· **Acute toxicity** *Based on available data, the classification criteria are not met.*

· **LD/LC50 values relevant for classification:**

Oral	LD0	>2,000 mg/kg (rat)
	LD 50 (Intraperitoneal)	>2,000 mg/kg (rat)

· **Primary irritant effect:**

· **Skin corrosion/irritation**

Causes skin irritation.

· **Serious eye damage/irritation**

Causes serious eye irritation.

· **Respiratory or skin sensitisation** *Based on available data, the classification criteria are not met.*

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

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Version number 1

Revision: 29.05.2019

Product name: Bicalutamide

(Contd. from page 5)

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Repr. 1B
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
May damage fertility. May damage the unborn child.
- **STOT-single exposure**
May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**
Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Not applicable
- **ADR, ADN, IMDG, IATA** Not applicable

(Contd. on page 7)

Safety data sheet
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Product name: Bicalutamide

(Contd. from page 6)

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| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Not applicable |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Not applicable |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Not applicable |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I Substance is not listed.**
- **15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**

SECTION 16: Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Repr. 1B: Reproductive toxicity – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31

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Version number 1

Revision: 29.05.2019

Product name: Bicalutamide

(Contd. from page 7)

· Sources

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

· **Data compared to the previous version altered.** All sections have been updated.

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