

1.) Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name

Bicalutamide 50 mg Film-coated tablets / Bicalutamide 150 mg Film coated tablets

Use of the substance/preparation

pharmaceutics

Company/undertaking identification

Address

medac Gesellschaft für klinische Spezialpräparate mbH
Fehlandtstrasse 3
20354 Hamburg

Telephone no. +49-4103-8006-0

Fax no. +49-4103-8006-100

Information provided by / telephone

Wedel site: Tel: +49 (4103)-8006-0; Fax: +49 (4103)-8006-100

Emergency telephone

+49(0)551 / 19240 {Giftinformationszentrum Nord (GIZ-Nord)} (Service in english)

Advice on Safety Data Sheet

sdb_info@umco.de

2.) Hazards identification

Hazard symbols

- N O N E

Particular information pertaining specific risk for human / environment

The product does not require a hazard warning label in accordance with Directive 1999/45/EC. No special hazards have to be mentioned. But please observe the information given in this safety data sheet.

3.) Composition / information on ingredients

Chemical characterization

Mixture (preparation)

Additional ingredients:

bicalutamide (INN)

EC no.	-	Index no.	-	CAS no.	90357-06-5
Concentration	> 30	< 50	%-b.w.		
Classification	-				
Hazard symbols	-	R phrases	-		

4.) First aid measures

General information

In case of persisting adverse effects, consult a physician. Change contaminated, saturated clothing.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air.

After skin contact

Wash off immediately with soap and water.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion

Seek medical advice immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

5.) Fire-fighting measures

Suitable extinguishing media

Foam; Carbon dioxide; extinguishing powder; Water spray jet

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases

In the event of fire, the following can be released:

Carbon dioxide (CO₂)

Carbon monoxide (CO)

Fire gas of organic material has to be classed invariably as respiratory poison.

Special protective equipment for fire-fighters

Use self-contained breathing apparatus. Wear protective clothing.

6.) Accidental release measures

Personal precautions

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Avoid dust formation. Keep away sources of ignition.

Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

Methods for cleaning up/taking up

Pick up mechanically. When picked up, treat material as prescribed under heading "Disposal considerations".

7.) Handling and storage

Handling

Advice on safe handling

No special measures necessary if stored and handled as prescribed. Avoid the formation and deposition of dust. Provide good ventilation of working area (local exhaust ventilation, if necessary).

Advice on protection against fire and explosion

Dust can form an explosive mixture with air. Take precautionary measures against static charges. Keep away from sources of heat and ignition.

Storage

Requirements for storage rooms and vessels

Store product in closed containers.

Advice on storage assembly

None known

Further information on storage conditions

Keep container tightly closed and dry in a cool, well-ventilated place.

8.) Exposure controls / personal protection

Exposure limit values

N O N E

Personal protective equipment

Respiratory protection

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn.

Hand protection

In case of intensive contact, wear protective gloves (EN 374). Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective glove should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Eye protection

Safety glasses (EN 166)

Skin protection

Clothing as usual in the chemical industry.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work. Have eye wash fountain available. Do not inhale dust.

9.) Physical and chemical properties

General information

Form	Tablets
Colour	white
Odour	odourless

Important health, safety and environmental information

Solubility in water

Remarks slightly soluble

Octanol/water partition coefficient (log Pow)

Value 2,49

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10.) Stability and reactivity

Conditions to avoid

None, if handled according to order.

Materials to avoid

None known.

Hazardous decomposition products

No hazardous decomposition products known.

Thermal decomposition

Remarks No decomposition if used as prescribed.

11.) Toxicological information

Acute toxicity

Acute oral toxicity

LD50 > 2000 mg/kg
Species rat

Acute dermal toxicity

Remarks No data available.

Acute inhalational toxicity

Remarks No data available.

Effects after repeated or prolonged exposition (subacute, subchronic, chronic)

Mutagenicity

Type of examination	In vitro mammalian cell gene mutation test
Species	Salmonella typhimurium
Value	negative
Type of examination	In vitro mammalian cytogenicity
Species	Chinese Hamster Ovary (CHO-K1) cells
Value	negative

Reproduction toxicity

Remarks Indications of toxic effects are available from reproduction studies in animals.

Carcinogenicity

Value Indications of possible carcinogenic effects in animal studies are available.

Experience in practice

Highly effective pharmaceutical agent.

Other information (chapter 11.)

The values mentioned are those of the active ingredient.

12.) Ecological information

Ecotoxicity

Fish toxicity

LC50 > 100 mg/l
Species rainbow trout
Duration of exposure 96 h

Daphnia toxicity

EC50 > 5,3 mg/l
Species Daphnia magna
Duration of exposure 48 h

Persistence and degradability

Biodegradability

Value 23 %
Duration of exposure 28 d
Evaluation not readily biodegradable

Bioaccumulative potential

Remarks Not potentially bioaccumulative.

Other adverse effects

Do not discharge product unmonitored into the environment.
The ecological data given are those of the active ingredient.

13.) Disposal considerations

Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the

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regional waste disposal company.

Packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

14.) Transport information**Other information (chapter 14.)**

The product is not defined under national/international road, rail, sea and air transport regulations as a hazardous material.

15.) Regulatory information**Labelling in accordance with EC directives**

The product does not require a hazard warning label in accordance with EC Directive 1999/45/EC.

Hazard symbols

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N O N E

Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Remarks	Annex I, part 1 + 2: not mentioned. With regard to possibly appropriate decomposition products see Chapter 10.
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16.) Other information**Sources of key data used to compile the data sheet:**

EC Directive 67/548/EC resp. 99/45/EC as amended in each case.

Regulation (EC) No 1907/2006 (REACH) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC as amended in each case.

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Department issuing safety data sheet

UMCO Umwelt Consult GmbH

Georg-Wilhelm-Str. 183 b, D-21107 Hamburg

Tel.: +49 40 / 41 92 13 00 Fax: +49 40 / 41 92 13 57 e-mail: umco@umco.de

This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.