

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0014490-FLUTAMIDE



Version 1 Date of compilation: 10/12/2019

Version 3 (replaces version 2)

Revision date: 27/10/2023

Page 1 of 9

Print date: 27/10/2023

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: FLUTAMIDE
Product Code: M0014490
Chemical Name: Flutamide
CAS No: 13311-84-7
EC No: 236-341-9

1.2 Relevant identified uses of the substance or mixture and uses advised against.

Raw material for master formulation

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **ACOFARMA DISTRIBUCIÓN S.A.**
Address: C/ Llobregat, 20, Pol. Ind. Santa Margarita
City: Terrassa
Province: Barcelona
Telephone: 902362203
Fax: 937360090
E-mail: atencioncliente@acofarma.com
Web: www.acofarma.es

1.4 Emergency telephone number: 902362203 (Only available during office hours; Monday-Friday; 09:00-18:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008:

Acute Tox. 4 : Harmful if swallowed.
Repr. 2 : Suspected of damaging fertility or the unborn child.
Carc. 2 : Suspected of causing cancer.
Aquatic Chronic 2 : Toxic to aquatic life with long lasting effects.
Eye Irrit. 2 : Causes serious eye irritation.
Acute Tox. 4 : Harmful if inhaled.

2.2 Label elements.

Labelling in accordance with Regulation (EC) No 1272/2008:

Pictograms:



Signal Word:

Warning

Hazard statements:

H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H351	Suspected of causing cancer.
H361d	Suspected of damaging the unborn child.
H411	Toxic to aquatic life with long lasting effects.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0014490-FLUTAMIDE



Version 1 Date of compilation: 10/12/2019

Version 3 (replaces version 2)

Revision date: 27/10/2023

Page 2 of 9

Print date: 27/10/2023

Precautionary statements:

P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P263	Avoid contact during pregnancy and while nursing.
P271	Use only outdoors or in a well-ventilated area.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

2.3 Other hazards.

The substance is not PBT

The substance is not vPvB

Substance does not have endocrine disrupting properties.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Mono-constituent.

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 13311-84-7 EC No: 236-341-9	Flutamide	55 - 100 %	Acute Tox. 4, H332 - Acute Tox. 4, H302 - Aquatic Chronic 2, H411 - Carc. 2, H351 - Eye Irrit. 2, H319 - Repr. 2, H361	-

3.2 Mixtures.

Not applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration. Do not administer anything orally. If unconscious, place them in a suitable position and seek medical assistance. The use of personal protective equipment is recommended for people providing first aid (see section 8).

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Don't let the person to rub the affected eye.

Skin contact.

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0014490-FLUTAMIDE



Version 1 Date of compilation: 10/12/2019

Version 3 (replaces version 2)

Revision date: 27/10/2023

Page 3 of 9

Print date: 27/10/2023

Irritant Product, repeated or prolonged contact with skin or mucous membranes can cause redness, blisters or dermatitis, inhalation of spray mist or particles in suspension may cause irritation of the respiratory tract, some symptoms may not be immediate.

Harmful Product, prolonged exposure due to inhalation may cause anaesthetic effects and the need for immediate medical assistance.

Long-term chronic exposure may result in injury to certain organs or tissues.

4.3 Indication of any immediate medical attention and special treatment needed.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

SECTION 5: FIREFIGHTING MEASURES.

The product is NOT classified as flammable, in case of fire the following measures should be taken:

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.

Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways. Product residues and extinguishing media may contaminate the aquatic environment.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product dangerous for the environment, in case of large spills or if the product contaminates lakes, rivers, or sewers, inform the responsible authorities according to local legislation. Prevent the contamination of drains, surface or subterranean waters, and the ground.

6.3 Methods and material for containment and cleaning up.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

For personal protection, see section 8.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0014490-FLUTAMIDE



Version 1 Date of compilation: 10/12/2019

Version 3 (replaces version 2)

Revision date: 27/10/2023

Page 4 of 9

Print date: 27/10/2023

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe indications on the label. Store the containers between 5 and 25 ° C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Raw material for compounding

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:		100 %	
Uses:		Raw material for master formulation	
Breathing protection:			
PPE:	Particle filter mask		
Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.		
CEN standards:	EN 149		
Maintenance:	Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it should be replaced after use.		
Observations:	Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding suitable use of the equipment.		
Filter Type needed:	P2		
Hand protection:			
PPE:	Protective gloves against chemicals.		
Characteristics:	«CE» marking, category III.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.		
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
PPE:	Protective goggles against particle impacts.		
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
Skin protection:			
PPE:	Protective clothing.		

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0014490-FLUTAMIDE



Version 1 Date of compilation: 10/12/2019

Version 3 (replaces version 2)

Revision date: 27/10/2023

Page 5 of 9

Print date: 27/10/2023

Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.
CEN standards:	EN 340
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.
PPE:	Work footwear.
Characteristics:	«CE» marking, category II.
CEN standards:	EN ISO 13287, EN 20347
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Solid - Dust
Colour: White or almost white
Odour: not applicable
Odour threshold: Not applicable
Melting point: 111-113 °C
Freezing point: 111-113 °C
Boiling point or initial boiling point and boiling range: Not available
Flammability: Not applicable
Lower explosion limit: Not applicable
Upper explosion limit: Not applicable
Flash point: Not available
Auto-ignition temperature: Not applicable
Decomposition temperature: Not available
pH: Not applicable (Substance/mixture is non-soluble (in water)).
Kinematic viscosity: Not applicable
Solubility: Freely soluble in alcohol and acetone
Hydrosolubility: not soluble in water
Liposolubility: Not available
Partition coefficient n-octanol/water (log value): Not available
Vapour pressure: Not available
Absolute density: Not available
Relative density: Not available
Relative vapour density: Not applicable
Particle characteristics: Not available

9.2 Other information

Not applicable/Not available due to the nature/properties of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0014490-FLUTAMIDE



Version 1 Date of compilation: 10/12/2019

Version 3 (replaces version 2)

Revision date: 27/10/2023

Page 6 of 9

Print date: 27/10/2023

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

IRRITANT MIXTURE. Splashes in the eyes can cause irritation.

11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

There are no tested data available on the product.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

a) acute toxicity;

Product classified:

Acute toxicity (Dermal), Category 4: Harmful in contact with skin.

Acute toxicity (Inhalation), Category 4: Harmful if inhaled.

Acute toxicity (Oral), Category 4: Harmful if swallowed.

Acute Toxicity Estimate (ATE):

Mixtures:

ATE (Dermal) = 1.100 mg/kg

ATE (Inhalation) = 2 mg/l/4 h (Dust or mist)

ATE (Oral) = 500 mg/kg

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

Not conclusive data for classification.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Product classified:

Reproductive toxicant, Category 2: Suspected of damaging fertility or the unborn child.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Not conclusive data for classification.

j) aspiration hazard;

Not conclusive data for classification.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity.

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0014490-FLUTAMIDE



Version 1 Date of compilation: 10/12/2019

Version 3 (replaces version 2)

Revision date: 27/10/2023

Page 7 of 9

Print date: 27/10/2023

12.2 Persistence and degradability.

No information is available regarding the biodegradability

No information is available on the degradability

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation.

12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transport following ADR rules for road transport, RID rules for railway, ADN for inner waterways, IMDG for sea, and ICAO/IATA for air transport.

Land: Transport by road: ADR, Transport by rail: RID.

Transport documentation: Consignment note and written instructions

Sea: Transport by ship: IMDG.

Transport documentation: Bill of lading

Air: Transport by plane: ICAO/IATA.

Transport document: Airway bill.

14.1 UN number or ID number.

UN No: UN2811

14.2 UN proper shipping name.

Description:

ADR/RID: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS FLUTAMIDE), 6.1, PG III, (E)

IMDG: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS FLUTAMIDE), 6.1, PG III, MARINE POLLUTANT

ICAO/IATA: UN 2811, TOXIC SOLID, ORGANIC, N.O.S. (CONTAINS FLUTAMIDE), 6.1, PG III

14.3 Transport hazard class(es).

Class(es): 6.1

14.4 Packing group.

Packing group: III

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0014490-FLUTAMIDE



Version 1 Date of compilation: 10/12/2019

Version 3 (replaces version 2)

Revision date: 27/10/2023

Page 8 of 9

Print date: 27/10/2023

14.5 Environmental hazards.

Marine pollutant: Yes



Dangerous for the environment

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-A,S-A

14.6 Special precautions for user.

Labels: 6.1



Hazard number: 60

Provisions concerning carriage in bulk ADR:

VC1 Carriage in bulk in sheeted vehicles, sheeted containers or sheeted bulk containers is permitted.

VC2 Carriage in bulk in closed vehicles, closed containers or closed bulk containers is permitted.

AP7 Carriage in bulk shall only be as a full load.

Proceed in accordance with point 6.

ADR LQ: 5 kg

IMDG LQ: 5 kg

ICAO LQ: 10 kg

14.7 Maritime transport in bulk according to IMO instruments.

The product is not transported in bulk.

SECTION 15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Classification codes:

Acute Tox. 4 : Acute toxicity (Inhalation), Category 4

Acute Tox. 4 : Acute toxicity (Oral), Category 4

Aquatic Chronic 2 : Chronic effect to the aquatic environment, Category 2

Carc. 2 : Carcinogen, Category 2

Eye Irrit. 2 : Eye irritation, Category 2

Repr. 2 : Reproductive toxicant, Category 2

-Continued on next page.-

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

M0014490-FLUTAMIDE



Version 1 Date of compilation: 10/12/2019

Version 3 (replaces version 2)

Revision date: 27/10/2023

Page 9 of 9

Print date: 27/10/2023

Changes regarding to the previous version:

- Change in the hazard classification (SECTION 2.1).
- Removal of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Addition of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Changes in the composition of the product (SECTION 3.2).
- Modifications in the first aid measures (SECTION 4.1).
- Modification of the symptoms (SECTION 4.2).
- Modification in the firefighting measures (SECTION 5.3).
- Modifications in the accidental release measures (SECTION 6.1).
- Modifications in the handling and storage precautions (SECTION 7.1).
- Modifications in the handling and storage precautions (SECTION 7.2).
- Modification of the information of the stability and reactivity conditions (SECTION 10.6).
- Modification of the classification ADR/IMDG/ICAO/IATA/RID (SECTION 14).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Abbreviations and acronyms used:

ADR/RID: Agreement concerning the International Carriage of Dangerous Goods by Road.

CEN: European Committee for Standardization.

PPE: Personal protection equipment.

IATA: International Air Transport Association.

ICAO: International Civil Aviation Organization.

IMDG: International Maritime Code for Dangerous Goods.

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.