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3.0

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

1.1. Product identifier

Trade name: Flutamide **CAS-number:** 13311-84-7

Reach registration number: NA

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

The uses of the chemical: Active pharmaceutical ingredients

Classification of the economic activities (NACE): 212
Use categories (UC62): 41

1.3. Details of the supplier of the safety data sheet:

Manufacturer/importer: Fermion Oy

Street address: Koivu-Mankkaan tie 6 A

Post-office box: P.O. Box 28

Postcode: 02101 Espoo, Finland

Telephone number: +358 10 4261 **Telefax:** +358 0 9452 1764

E-mail address: chemicalsafety@orion.fi

VAT Reg. No: FI18552129

1.4. Emergency telephone number

Poison Center: +358 9 471 977

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to regulation EC 1272/2008	Acute Tox. 4	H302,
	Repr. 1A	H360F,
H Statements	Harmful if swallowed.	
	May damage fertility.	



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2.2. Label elements

Hazard Pictograms



Signal word Danger

H Statements

H302 Harmful if swallowed. H360F May damage fertility.

P Statements

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor. P308+P313 IF exposed or concerned: Get medical advice/attention. P501 Dispose of contents according to national and local law.

2.3. Other hazards

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Flutamide	13311-84-7	236-341-9	NA

Request for Confidentiality by Annex 2 No

Substance indicated Confidential No

Other information -



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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions Helpers should ensure their own protection.

Inhalation IF INHALED: Remove victim to fresh air and keep at

rest in a position comfortable for breathing.

If appropriate, give oxygen.

If appropriate, give artificial respiration.

Get medical advice/attention.

Skin contact Remove/Take off immediately all contaminated

clothing.

IF ON SKIN: Wash with soap and water. If skin irritation occurs: Get medical

advice/attention.

Eye contact IF IN EYES: Rinse continuously with water for several

minutes. Get medical advice/attention.

Ingestion Induce vomiting.

If the patient is conscious, give plenty of water (2 - 4 glasses), and let the charcoal (approximately 20 tablets), or give activated charcoal slurry (2 - 4

glasses).

Get medical advice/attention.

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

See section 11 for symptoms of exposure.

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

Data not available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media Powder

Foam



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> Carbon dioxide Water

5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of hydrogen fluoride and oxides of carbon and nitrogen during heating or fire.

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters

Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required. Access of extra people to the spill area must be prevented.

6.2. Environmental precautions

Data not available.

6.3. Methods and material for containment and cleaning up

Collect spilled powder without dusting into tight closed container.

6.4. Reference to other sections

See Section 8 and 13



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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in well-ventilated space.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

Store in a dry place.

Keep cool.

Protect from sunlight.

7.3. Specific end use(s)

No information identified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

International OEL values -

DNELs -

PNECs -

8.2. Exposure controls

Appropriate engineering controls

All exposure must be avoided.

Handle in closed systems or use an efficient local exhaust if vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal protective equipment. Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid contact during pregnancy/while nursing.

Respiratory protection

In dust making work use respirator, filtration P3.In laboratories work in fume hood or under dust control hood.

See particular department's regulations of protection.

Hand protection

Use protective gloves (e.g. nitrile or neopren gloves).

Eye protection





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Use protective goggles.

Skin protection

In dust making work use disposal overalls and extra throwaway sleeves.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state Crystalline / Powder

ColourYellowOdour-Odour threshold-

9.1. Information on basic physical and chemical properties

Melting point 111 - 113 °C

Water solubility Insoluble

Soluble in acetone, ethanol

9.2. Other information

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SECTION 10: STABILITY AND REACTIVITY

10.1.Reactivity

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10.2. Chemical stability

Stable when stored and handled according to instructions of use.

10.3. Possibility of hazardous reactions

Not expected to occur.



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10.4. Conditions to avoid

Light

10.5. Incompatible materials

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10.6 Hazardous decomposition products

May emit toxic fumes of hydrogen fluoride and oxides of carbon and nitrogen during heating or fire.

SECTION 11: TOXICOLOCIGAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed.

LD50 = 787 mg/kg (rat, oral) LDLO = 1000 mg/kg (rat, oral)

LD50 = 120 mg/kg (mouse, intraperitoneal)

Skin irritation and corrosion Data not available.

Skin sensitization Data not available.

Serious eye damage and irritation Data not available.

Respiratory irritation Data not available.

Respiratory sensitization Data not available.

Carcinogenicity Data not available.

Germ cell mutagenicity Data not available.

Reproductive toxicity May damage fertility.

STOT-single exposure Data not available.

STOT-repeated exposure Data not available.



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Aspiration hazard Data not available.

Repeated dose toxicityData not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Data not available.

Toxic effects on other organisms

Data not available.

12.2.Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Octanol-water partition coefficient(KOW) Data not available.

Bioconcentration factor Data not available.

12.4. Mobility in soil

Data not available.





Effective Date 11.12.2015 Revision 5.0 12.5. Results of PBT and vPvB assessment Data not available. 12.6. Other adverse effects Data not available. **SECTION 13: DISPOSAL CONSIDERATIONS** 13.1. Waste treatment methods Chemicals must be disposed of in compliance with the respective national regulations. **SECTION 14: TRANSPORT INFORMATION** 14.1. UN Number 14.2. UN Proper shipping name 14.3. Transport hazard class(es) (ADR/RID,IMDG,ICAO/IATA) This product is not regulated under the transport regulations. 14.4. Packing group 14.5. Environmental hazard 14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable



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SECTION 15: REGULATORY INFORMATION

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

The product has not been fully tested.

15.2. Chemical Safety Assessment

No

SECTION 16: OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Fermion Oy shall not be held liable for any damage resulting from handling or from contact with the above product.

Sources of key data used to compile the Safety Data Sheet

Information provided by the supplier

Information which has been added, deleted or revised

Updated section / sections:

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