

Effective Date 15.6.2011
Supersedes 30.6.2006

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

1.1. Product identifier

Trade name: Ospemifene

Reach registration number: -

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 9 452 1764
E-mail address: chemicalsafety@orion.fi
VAT Reg. No: FI1855212-9

1.4. Emergency telephone number

Poison Center +358 9 471 977

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to regulation EC 1272/2008 According to the knowledge available it is not classified as harmful substances.

2.3. Other hazards

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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Hazardous ingredients

Name of the ingredient	CAS-number	EC-number	Reach registration number:	Concentration / Limit	Classification according to regulation EC 1272/2008	Classification according to Directive 67/548/EEC
Ospemifene Z-2-[4-(4-Chloro-1,2-diphenyl-but-1-enyl)phenoxy] ethane C ₂₆ H ₂₃ ClO ₂	128607-22-7	-	-	ca 100 %	-	-

Other information

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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. Get medical advice/attention.

Skin contact

Remove/Take off immediately all contaminated clothing.
IF ON SKIN: Wash with soap and water. Get medical advice/attention.

Eye contact

IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.

Ingestion

Get medical advice/attention.

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

Data not available.

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

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5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	Carbon dioxide Foam Powder
Unsuitable extinguishing media	Do not use water

5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of hydrogen chloride 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.
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Other instructions

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6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.

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

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in well-ventilated space.
Avoid dust formation.

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All exposure must be avoided.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed.
See incompatible materials in section 10.5.

7.3. Specific end use(s)

No information identified.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

International OEL values	Data not available.
DNELs	Data not available.
PNECs	Data not available.

8.2. Exposure controls

Appropriate engineering controls

Use only outdoors or in a well-ventilated area.
Take precautionary measures against static discharge.
Ground/bond container and receiving equipment.
Do not get in eyes, on skin, or on clothing.
Wash up thoroughly after handling (shower).

Respiratory protection

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

Hand protection

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

Eye protection

Use protective goggles.

Skin protection

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

Environmental exposure controls

The environmental characteristics of this substance have not been fully investigated.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state Powder
Colour White
Odour -

9.1. Information on basic physical and chemical properties

pH Value	-
Melting point	117 °C
Freezing point	-
Boiling point	-
Boiling Range	-
Flash point	-
Evaporation rate	-
Flammability (solid, gas)	-
Upper explosive limit	-
Lower explosive limit	-
Vapour pressure	-
Vapour density	-
Relative density	-
Water solubility	Insoluble
Fat solubility	-
Partition coefficient: n-octanol/water	-
Auto-ignition temperature	-
Decomposition temperature	-
Viscosity	-
Explosive properties	-

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Oxidizing properties -

9.2. Other information

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10. STABILITY AND REACTIVITY

10.1. Reactivity

Data not available.

10.2. Chemical stability

Stable when stored and handled according to instructions of use.

10.3. Possibility of hazardous reactions

Not expected to occur.

10.4. Conditions to avoid

Data not available.

10.5. Incompatible materials

Oxidants
Strong acids

10.6. Hazardous decomposition products

May emit toxic fumes of hydrogen chloride during heating or fire.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity	LD ₅₀ > 2000 mg/kg (rat, oral)
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.

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Carcinogenicity	Data not available.
Germ cell mutagenicity	Data not available.
Reproductive toxicity	Data not available.
STOT-single exposure	Data not available.
STOT-repeated exposure	Data not available.
Repeated dose toxicity	Data not available.

12. ECOLOGICAL INFORMATION

12.1. Toxicity

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.

12.5. Results of PBT and vPvB assessment

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12.6. Other adverse effects

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13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

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14. TRANSPORT INFORMATION

14.1. UN Number

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14.2. UN proper shipping name

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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 hazards

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14.6. Special precautions for users

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

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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

16. OTHER INFORMATION

List of relevant R and S phrases and H and P statements

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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

Hormos Medical, Turku, Finland

Information which has been added, deleted or revised

Added the classification according to regulation 1272/2008/EC (CLP).