

Effective Date 25.01.2018  
Revision 5.0

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

#### 1.1. Product identifier

Trade name: Quetiapine Fumarate  
CAS-number: 111974-72-2

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 9 452 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) No 1272/2008	Acute Tox. 4 Eye Irrit. 2 STOT SE 3 Aquatic Chronic 3	H302, H319, H336, H412,
H Statements	Harmful if swallowed. Causes serious eye irritation. May cause drowsiness or dizziness. Harmful to aquatic life with long lasting effects.	

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### 2.2. Label elements

#### Hazard Pictograms



Signal word

Warning

#### H Statements

- H302 Harmful if swallowed.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.
- H412 Harmful to aquatic life with long lasting effects.

#### P Statements

- P280 Wear protective gloves/protective clothing/eye protection.
- P305+P351+P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do, continue rinsing.
- P273 Avoid release to the environment.

### 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:
Quetiapine Fumarate	111974-72-2	-	NA

Other information

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### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of first aid measures

<b>Special instructions</b>	Helpers should ensure their own protection.
<b>Inhalation</b>	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If appropriate, give artificial respiration. Get medical advice/attention.
<b>Skin contact</b>	Remove/Take off immediately all contaminated clothing. IF ON SKIN: Wash with soap and water. If skin irritation occurs: Get medical advice/attention.
<b>Eye contact</b>	IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
<b>Ingestion</b>	Rinse mouth. 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

<b>Suitable extinguishing media</b>	Powder Carbon dioxide Foam Water
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### 5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of oxides of carbon, nitrogen and sulphur during heating or fire.

### 5.3. Advice for fire-fighters

**Special protective equipment for fire-fighters** Isolating breathing apparatus eg. compressed breathing apparatus and isolating protective clothing.

## SECTION 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

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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.

See incompatible materials in section 10.5.

### 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

Handle in well-ventilated space.

Do not get in eyes, on skin, or on clothing.

Avoid breathing dust/fume/gas/mist/vapours/spray.

#### Respiratory protection

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

Use protective goggles.

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**Skin protection**

Wear protective clothing.

**Environmental exposure controls**

Avoid release to the environment.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES****Appearance**

Physical state	Powder
Colour	White
Odour	Odourless
Odour threshold	-

**9.1. Information on basic physical and chemical properties**

Melting point	171 - 174 °C
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Water solubility	Slightly soluble
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Partition coefficient: n-octanol/water (logP)	< 1,1
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**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

Moisture

#### 10.5. Incompatible materials

Oxidants

#### 10.6 Hazardous decomposition products

May emit toxic fumes of oxides of carbon, nitrogen and sulphur during heating or fire.

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	Harmful if swallowed. Findings in mice and rats after oral (500 mg/kg) or intraperitoneal (100 mg/kg) dosing were typical of an effective neuroleptic agent and included decreased motor activity, ptosis, loss of righting reflex, fluid around the mouth and convulsions. LD50: 2000 mg/kg (rat, oral) LDLo: 70 mg/kg (human, oral)
<b>Skin irritation and corrosion</b>	Data not available.
<b>Skin sensitization</b>	Data not available.
<b>Serious eye damage and irritation</b>	Causes serious eye irritation.
<b>Respiratory irritation</b>	Data not available.
<b>Respiratory sensitization</b>	Data not available.
<b>Carcinogenicity</b>	There is no evidence of carcinogenicity.
<b>Germ cell mutagenicity</b>	There is no evidence of mutagenicity.
<b>Reproductive toxicity</b>	No teratogenic effects detected.

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<b>STOT-single exposure</b>	May cause drowsiness or dizziness.
<b>STOT-repeated exposure</b>	Data not available.
<b>Aspiration hazard</b>	Data not available.
<b>Repeated dose toxicity</b>	In multiple-dose studies in rats, dogs and monkeys, anticipated central nervous system effects of an antipsychotic drug were observed with quetiapine (e.g. sedation at lower doses and tremor, convulsions or prostration at higher exposures).

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### Aquatic toxicity

Harmful to aquatic life with long lasting effects.

LC50(96 h): 19,3-22 mg/l, fish

EC50(48 h): 10-100 mg/l, daphnia

ErC50(72 h): 10-100 mg/l, algae

#### Toxic effects on other organisms

Data not available.

### 12.2.Persistence and degradability

Not readily biodegradable.

### 12.3. Bioaccumulative potential

**Octanol-water partition coefficient** According to logP value this compound is not bioaccumulative.

**Bioconcentration factor** Data not available.



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#### 12.4. Mobility in soil

Data not available.

#### 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

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.

### SECTION 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 hazard

-

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#### 14.6. Special precautions for user

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

Not applicable

### 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:

2, 9, 11, 12