

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form	: Substance
Trade name	: QUETIAPINE FUMARATE
Chemical name	: 2-(2-(4-dibenzo(b,f)(1,4)thiazepin-11-yl-1-piperazinyl)ethoxy-ethanol fumarate (2:1)
IUPAC name	: 2-(2-(4-dibenzo(b,f)(1,4)thiazepin-11-yl-1-piperazinyl)ethoxy-ethanol fumarate (2:1)
CAS-No.	: 111974-72-2
Product code	: 15712.QFT
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C46H54N6O8S2
Synonyms	: 2-[2-(4-dibenzo[b,f][1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]-ethanol, (2E)-2-butenedioate(2:1) (salt)
Other means of identification	: OCCOCCN1CCN(CC1)C1=NC2=CC=CC=C2SC2=CC=CC=C12 (Quetiapine free base)

**1.2. Relevant identified uses of the substance or mixture and uses advised against****1.2.1. Relevant identified uses**

Main use category	: API, Industrial use, Medicinal use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use For professional use only Industrial
Use of the substance/mixture	: Antipsychotic
Function or use category	: Pharmaceuticals

**1.2.2. Uses advised against**

No additional information available

**1.3. Details of the supplier of the safety data sheet****Supplier**

MOEHS IBÉRICA, S.L.  
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[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**Manufacturer**

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**Manufacturer**

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[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**1.4. Emergency telephone number**

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Acute toxicity (oral), Category 4	H302
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	H335

Full text of H statements : see section 16

# QUETIAPINE FUMARATE

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

### Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Causes serious eye irritation. May cause respiratory irritation.

### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H302 - Harmful if swallowed  
H319 - Causes serious eye irritation  
H335 - May cause respiratory irritation

Precautionary statements (CLP) :

P261 - Avoid breathing dust, gas, fume, mist, vapours, spray  
P264 - Wash hands, forearms and face thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P271 - Use only outdoors or in a well-ventilated area  
P280 - Wear eye protection, face protection  
P301+P312 - IF SWALLOWED: Call a POISON CENTER if you feel unwell  
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P330 - Rinse mouth  
P337+P313 - If eye irritation persists: Get medical advice/attention  
P403+P233 - Store in a well-ventilated place. Keep container tightly closed  
P405 - Store locked up  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

### 2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

vPvB: not relevant – no registration required

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
QUETIAPINE FUMARATE	(CAS-No.) 111974-72-2	100

Full text of R- and H-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation : Assure fresh air breathing.  
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.  
First-aid measures after eye contact : Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for several minutes. Consult an ophthalmologist if irritation persists.  
First-aid measures after ingestion : Rinse mouth out with water. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

Never give anything by mouth to an unconscious person.

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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

- Suitable extinguishing media : Water spray. Foam. Dry powder. Carbon dioxide. Sand. Do not use a solid water stream as it may scatter and spread fire.
- Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

#### 5.2. Special hazards arising from the substance or mixture

- Fire hazard : In case of fire and/or explosion do not breathe fumes.

#### 5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

##### 6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.

#### 6.2. Environmental precautions

- Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

#### 6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust.

#### 6.4. Reference to other sections

- For further information refer to section 8: "Exposure controls/personal protection".

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Precautions for safe handling : Provide local exhaust or general room ventilation.
- Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

#### 7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Keep in a cool, well-ventilated place away from heat.
- Storage conditions : Store in a well-ventilated place. Keep cool. Keep container closed when not in use.
- Incompatible products : Strong acids. Strong bases.
- Incompatible materials : Direct sunlight. Sources of ignition.
- Storage area : Store in a well-ventilated place.

#### 7.3. Specific end use(s)

- No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

- Additional information : MOEHS occupational exposure band : 3 (0.01 - 0.1 mg/m<sup>3</sup>)

#### 8.2. Exposure controls

##### Personal protective equipment:

- Gloves. Safety glasses. Dust/aerosol mask with filter type P3.

##### Hand protection:

- In case of repeated or prolonged contact wear gloves

Type	Material	Standard
Disposable gloves	Natural rubber, Latex, Neoprene rubber (HNBR) , Fluoroelastomer (FKM) , Polyvinylchloride (PVC) , Polyvinylalcohol (PVA), Butyl rubber, Nitrile rubber (NBR)	EN 374

##### Eye protection:

- Chemical goggles or safety glasses

##### Respiratory protection:

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Dust formation: dust mask

Device	Filter type	Condition	Standard
Dust mask	Type P3	Dust protection	EN 143



## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Molecular mass	: 883.1 g/mol
Colour	: white.
Odour	: characteristic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 171 - 174 °C
Freezing point	: No data available
Boiling point	: 556.5 °C (@760mmHg)
Flash point	: ≈ 290.4 °C (Estimated by ACDLABS)
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: insoluble in water.
Log Pow	: 2.93 (Quetiapine base LogP According ALOGPS)
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

Minimum ignition energy	: < 1 mJ
Additional information	: Layer Minimum flammability Temperature : Melt. Dust Cloud minimum Flammability Temperature : 340. Explosivity Pmax [bar-g]: 8.9. Explosion Severity Factor Kmax (bar.m/s) : 290. Explosion Class : St 2

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

Extremely high or low temperatures. Direct sunlight.

### 10.5. Incompatible materials

Strong acids. Strong bases.

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### 10.6. Hazardous decomposition products

fume. On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide. Nitrogen oxides.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral) : Oral: Harmful if swallowed.  
Acute toxicity (dermal) : Not classified  
Acute toxicity (inhalation) : Not classified

#### QUETIAPINE FUMARATE (111974-72-2)

LD50 oral rat	2000 mg/kg
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

Acute aquatic toxicity : Not classified  
Chronic aquatic toxicity : Not classified

#### QUETIAPINE FUMARATE (111974-72-2)

Green algae EC50	8.03 mg/l (96 hr) growth rate
EC50	3.59 mg/l (96 hr) biomass
Bacteria aerobic: EC50	> 100 mg/l
NOEC	green algae 14 d: 2.5 mg/l
Additional information	: CL50 96H - Trucha arcoiris [mg/l] : 22. : EC50 48 H - Daphnia magna [mg/l]: 32

### 12.2. Persistence and degradability

#### QUETIAPINE FUMARATE (111974-72-2)

Persistence and degradability	Biodegradable.
Biodegradation	24 %

### 12.3. Bioaccumulative potential

#### QUETIAPINE FUMARATE (111974-72-2)

Log Pow	2.93 (Quetiapine base LogP According ALOGPS)
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

#### QUETIAPINE FUMARATE (111974-72-2)

vPvB: not relevant – no registration required
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### 12.6. Other adverse effects

Additional information : Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

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### 14.1. UN number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable
UN-No. (ADN)	: Not applicable
UN-No. (RID)	: Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

### 14.3. Transport hazard class(es)

#### ADR

Transport hazard class(es) (ADR)	: Not applicable
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#### IMDG

Transport hazard class(es) (IMDG)	: Not applicable
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#### IATA

Transport hazard class(es) (IATA)	: Not applicable
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#### ADN

Transport hazard class(es) (ADN)	: Not applicable
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#### RID

Transport hazard class(es) (RID)	: Not applicable
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### 14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

### 14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

### 14.6. Special precautions for user

#### - Overland transport

Not applicable

#### - Transport by sea

Not applicable

#### - Air transport

Not applicable

#### - Inland waterway transport

Not applicable

#### - Rail transport

Not applicable

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

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### SECTION 15: Regulatory information

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

##### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

QUETIAPINE FUMARATE is not on the REACH Candidate List

QUETIAPINE FUMARATE is not on the REACH Annex XIV List

##### 15.1.2. National regulations

###### Germany

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

###### Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

###### Denmark

Classification remarks : Emergency management guidelines for the storage of flammable liquids must be followed

Recommendations Danish Regulation : Young people below the age of 18 years are not allowed to use the product

#### 15.2. Chemical safety assessment

No additional information available

### SECTION 16: Other information

Full text of R-, H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed
H319	Causes serious eye irritation
H335	May cause respiratory irritation
R22	Harmful if swallowed
R36/37	Irritating to eyes and respiratory system
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II)

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*