

QUETIAPINI FUMARAS

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

1.1 Product identifier

Product name:	Quetiapine fumarate Quetiapini fumaras Quetiapine fumaraat Quétiapine (fumarate de) Quetiapin fumarat
N° CAS:	111974-72-2
N° EC:	601-144-2

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient.
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1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute toxicity (category 4)	H302
Harmful in contact with skin (category 4)	H312
Eye irritation (category 2)	H319
Harmful if inhaled (category 4)	H332
Reproductive toxicity (category 2)	H361
Aquatic acute (category 1)	H400
Aquatic long-term (category 1)	H413

2.2 Label elements

Labelling according to (EC) n° 1272/2008

QUETIAPINI FUMARAS

Hazard pictogram(s):



Signal word(s):

Attention

Hazard statements:

- | | |
|------|---|
| H302 | Harmful if swallowed. |
| H312 | Harmful in contact with skin. |
| H319 | Causes serious eye irritation. |
| H332 | Harmful if inhaled. |
| H361 | Suspected of damaging fertility or the unborn child. |
| H400 | Very toxic to aquatic life. |
| H413 | May cause long lasting harmful effects to aquatic life. |

Precautionary statements:

- | | |
|----------------|--|
| P203 | Obtain, read and follow all safety instructions before use. |
| P261 | Avoid breathing dust/fume/gas/mist/vapors/spray. |
| P264 | Wash hands [and ...] thoroughly after handling. |
| P264+P265 | Wash hands [and ...] thoroughly after handling. Do not touch eyes. |
| P270 | Do not eat, drink or smoke when using this product. |
| 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. |
| P301+P317 | If swallowed: Get medical help. |
| P302+P352 | If on skin: Wash with plenty of water. |
| 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. |
| P317 | Get emergency medical help. |
| P318 | If exposed or concerned, get medical advice. |
| P321 | Specific treatment (see section 4 on this label). |
| P330 | Rinse mouth. |
| P337+P317 | If eye irritation persists: Get medical help. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |
| P391 | Collect spillage. |
| P405 | Store locked up. |
| P501 | Dispose of contents/container to ... |

Additional applicable label elements:

Not applicable.

2.3 Other hazards

Not available.

QUETIAPINI FUMARAS

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Quetiapine fumarate
IUPAC name:	2-[2-(4-benzo[b][1,4]benzothiazepin-6-yl)piperazin-1-yl]ethoxy]ethanol;(E)-but-2-enedioic acid
Synonyms:	Quetiapine hemifumarate Utapine Ethanol, 2-[2-(4-dibenzo[b,f][1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]-, (2E)-2-butenedioate (2:1)
N° CAS:	111974-72-2
N° EC:	601-144-2
Molecular Formula:	C ₄₆ H ₅₄ N ₆ O ₈ S ₂
Content:	– quetiapine fumarate (C ₄₆ H ₅₄ N ₆ O ₈ S ₂ ; Mr 883): 99.0 per cent to 101.0 per cent (dried substance); – fumaric acid (C ₄ H ₄ O ₄ ; Mr 116.1): 12.5 per cent to 13.8 per cent (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Instructions for the doctor: There is no specific antidote. Therefore appropriate supportive measures should be instituted. Remove from exposure. Remove from contaminated clothing. Persons developing malaise must receive immediate medical attention.
After inhalation:	Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
After skin contact:	Immediately wash skin with soap and copious amounts of water for at least 15minutes. If irritation persists, seek medical attention.
After eye contact:	Immediately flush eyes with copious amounts of water for at least 15minutes. Seek medical advice.
After ingestion:	If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice. Gastric lavage (after intubation, if patient is unconscious) and administration of charcoal together with a laxative should be considered.
Self-protection of the first aider:	Not applicable.

QUETIAPINI FUMARAS

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, dry chemicals, carbon dioxide or foams appropriate for surrounding fire and materials.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

Hazardous combustion products: Particular dangers caused by exposition to substance, its combustion products or gases produced.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Wear approved respiratory and chemically compatible protecting gloves.

For emergency responders

Avoid contact with eyes, skin or clothing. Avoid breathing dust or mist. Wear approved respiratory and chemically compatible protecting gloves.

6.2 Environmental precautions

Do not allow entrance in sewage water, water suppliers or stretches of groundwater.

6.3 Methods and material for containment and cleaning up

Wear approved respirator and chemically compatible gloves. Vacuum or sweep up spillage. Avoid dust place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and sash spill site.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Not available.

QUETIAPINI FUMARAS

Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	The usual precautionary measures for dealing with chemicals should be observed. When using do not drink, eat or smoke. Avoid formation of dust.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in an airtight container at normal temperature.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection:	Wear splash-resistant safety goggles. Provide an emergency eye-wash fountain and a quick direct shower in the immediate work area.
Skin protection:	Wear appropriate chemical-resistant clothes.
Hand protection:	Wear appropriate chemical resistant gloves.
Respiratory protection:	Not determined.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white crystalline powder.
Odour:	Not available.
Odour threshold:	Not available.
pH:	5.0 - 6.0 (1.0 % suspension in water).
Melting/freezing point:	172 - 176° C
Initial boiling point:	Not available.

QUETIAPINI FUMARAS

Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in glacial acetic acid, sparingly soluble in methanol and ethanol.
Solubility in water:	Practically insoluble.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable under recommended storage conditions

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.
Substances to avoid: Oxidizing material.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Thermal decomposition or combustion products: oxides of carbon, oxides of nitrogen, oxides of sulphur.

SECTION 11: TOXICOLOGICAL INFORMATION

QUETIAPINI FUMARAS

11.1 Information on toxicological effects

LD ₅₀ (oral rat) [mg/Kg]	3550
LD ₅₀ (oral mouse) [mg/Kg]	730
Acute toxicity:	Not available.
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

QUETIAPINI FUMARAS

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber. Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product. Don't allow product to enter drinking water supplies; waste water or soil.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), UN3077
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Not classified.
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 9
IATA/ICAO (Air) :

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III
IATA/ICAO (Air) :

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not classified.
IATA/ICAO (Air) :

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.
Risk phrases: R20+21+22 Harmful by inhalation, in contact with skin and if swallowed.
Safety phrases: S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36 Wear suitable protective clothing.

15.2 Chemical safety assessment

QUETIAPINI FUMARAS

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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MATERIAL SAFETY DATA SHEET

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According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

PAGE 10 OF 10

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QUETIAPINI FUMARAS

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16.8 Department issuing MSDS

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