

Quetiapine Fumarate

Version: 5.2

Revision Date: 26.03.2025

SDS Number: 100000000040

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Quetiapine Fumarate
REACH Registration Number : NA
CAS-No. : 111974-72-2
Unique Formula Identifier : -

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

Use of the Sub-
stance/Mixture : Active pharmaceutical ingredients

Recommended restrictions : No data available
on use

1.3 Details of the supplier of the safety data sheet

Company : Fermion Oy
Street address : Koivu-Mankkaan tie 6 A
Post-office box: : P.O. Box 28
Postcode : 02101 Espoo, Finland
Telephone : +358 10 4261
E-mail address of person : chemicalsafety@orion.fi
responsible for the SDS
VAT Reg. No: : FI18552129

1.4 Emergency telephone number

Poison Center : +358 800 147111
+358 9 471 977

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture


Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Specific target organ toxicity - single exposure, Category 3	H336: May cause drowsiness or dizziness.
Long-term (chronic) aquatic hazard, Category 2	H412: Harmful to aquatic life with long lasting effects.

For explanation of abbreviations see section 16.

2.2 Label elements

Labeling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal Word : Warning

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Hazard 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.

Precautionary Statements

General:

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3 Other hazards

Other hazards	:	No data available
PBT	:	No data available
vPvB	:	No data available
Endocrine disrupting properties	:	Ecological information: No data available Toxicological information: No data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	CAS-No. EC-No. Registration-No	Concentration (% w/w)	M-Factor, SCL, ATE
Quetiapine fumarate	111974-72-2		

Other information : No data available

3.2 Mixtures

Not applicable

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice : Helpers should ensure their own protection.

If inhaled : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
If appropriate, give artificial respiration.

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Get medical advice/attention.

In case of 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.

In case of eye contact : IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.

If swallowed : Rinse mouth.
Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : See section 11 for symptoms of exposure.

Risks : No data available

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Powder
Carbon dioxide (CO₂)
Foam
Water

Unsuitable extinguishing media : No data available

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products : No data available

5.3 Advice for firefighters

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

Specific extinguishing methods : No data available

Further information : No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment as required.

6.2 Environmental precautions

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Environmental precautions : Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Collect spilled powder without dusting into tight closed container.

6.4 Reference to other sections

See Section 8 and 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Handle in well-ventilated space.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep container tightly closed.
Keep cool.
Keep in a dry place.
Protect from sunlight.
See incompatible materials in section 10.5.

Packaging material : Suitable material: No data available
Unsuitable material: No data available

7.3 Specific end use(s)

Specific use(s) : No information identified.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures : Handle in well-ventilated space.
Do not get in eyes, on skin, or on clothing.
Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
Handle in closed systems or use an efficient local exhaust if dust, vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal protective equipment.

Personal protective equipment

Respiratory protection : In open handling use respirator (P3) with a minimum protection factor of 200.
See standard working procedures/instructions or department's instructions for more detailed protection measures.

Eye/face protection : Use protective goggles.

Hand protection

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Remarks	:	Use protective gloves (e.g. nitrile or neopren gloves).
Skin and body protection	:	Wear protective clothing.
Protective measures	:	No data available
Environmental exposure controls	:	No data available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	:	powder
Physical state	:	solid
Color	:	white
Odor	:	odorless
Odor Threshold	:	No data available
Melting point/range	:	171 - 174 °C
Boiling point/boiling range	:	No data available
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Self-Accelerating decomposition temperature (SADT)	:	No data available
pH	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Flow time	:	No data available
Solubility(ies)		
Water solubility	:	slightly soluble
Solubility in other solvents	:	No data available

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Dissolution Rate	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: < 1,1
Dispersion Stability	:	No data available
Vapor pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	No data available
Relative vapor density	:	No data available
Dissociation constant	:	No data available
Particle characteristics	:	No data available

9.2 Other information

Self-ignition	:	No data available
Hygroscopic properties	:	No data available
Henry's Constant	:	No data available
Further information	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable when stored and handled according to instructions of use.

10.3 Possibility of hazardous reactions

Hazardous reactions : Not expected to occur.

10.4 Conditions to avoid

Conditions to avoid : moisture

10.5 Incompatible materials

Materials to avoid : Oxidants

10.6 Hazardous decomposition products

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

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Health hazard information : Harmful if swallowed.

Acute oral toxicity : LD50 (Rat): 2 000 mg/kg
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.

LDLo (Humans): 70 mg/kg

Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

Acute toxicity (other routes of administration) : No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

Result : Causes serious eye irritation.

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Genotoxicity in vitro : There is no evidence of mutagenicity.

Genotoxicity in vivo : No data available

Carcinogenicity

Remarks : There is no evidence of carcinogenicity.

Reproductive toxicity

Effects on fertility : No data available

Effects on fetal development : No teratogenic effects detected.

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STOT-single exposure

Assessment : May cause drowsiness or dizziness.

STOT-repeated exposure

No data available

Repeated dose toxicity

Remarks : 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).

Aspiration toxicity

No data available

11.2 Information on other hazards

Endocrine disrupting properties

No data available

Experience with human exposure

General Information : No data available

Inhalation : No data available

Skin contact : No data available

Eye contact : No data available

Ingestion : No data available

Toxicology, Metabolism, Distribution

Remarks : No data available

Neurological effects

Remarks : No data available

Further information

No data available

Other Health Hazards

No data available

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SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish	:	LC50 (Fish): 19,3 - 22 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia): 10 - 100 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (algae): 10 - 100 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	:	No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	No data available
Toxicity to microorganisms	:	No data available
Toxicity to soil dwelling organisms	:	No data available
Plant toxicity	:	No data available
Sediment toxicity	:	No data available
Toxicity to terrestrial organisms	:	No data available

Ecotoxicology Assessment

Acute aquatic toxicity	:	Harmful to aquatic life with long lasting effects.
Chronic aquatic toxicity	:	No data available
Toxicity Data on Soil	:	No data available
Other organisms relevant to the environment	:	No data available

12.2 Persistence and degradability

Biodegradability	:	Result: Not readily biodegradable.
Biochemical Oxygen Demand (BOD)	:	No data available
Chemical Oxygen Demand (COD)	:	No data available
BOD/COD	:	No data available
ThOD	:	No data available

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BOD/ThOD	:	No data available
Dissolved organic carbon (DOC)	:	No data available
Physico-chemical removability	:	No data available
Stability in water	:	No data available
Impact on Sewage Treatment	:	No data available
Photodegradation	:	No data available

12.3 Bioaccumulative potential

Bioaccumulation	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: < 1,1 According to logP value this compound is not bioaccumulative.

12.4 Mobility in soil

Mobility	:	No data available
Distribution among environmental compartments	:	No data available
Stability in soil	:	No data available

12.5 Results of PBT and vPvB assessment

Assessment	:	No data available
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12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

Environmental fate and pathways	:	No data available
Adsorbed organic bound halogens (AOX)	:	No data available
Ozone-Depletion Potential	:	No data available
Additional ecological information	:	No data available

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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

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

-

14.3 Transport hazard class(es) (ADR/RID, IMDG, ICAO/IATA)

ADR/RID: This product is not regulated under the transport regulations.

IMDG: This product is not regulated under the transport regulations.

IATA: This product is not regulated under the transport regulations.

14.4 Packing group

ADR/RID: -

IMDG: -

IATA: -

14.5 Environmental hazards

ADR/RID: -

IMDG: -

IATA: -

14.6 Special precautions for user

Tunnel restriction code : No data available

Further information for transport : No data available

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 the substance or mixture

The product has not been fully tested.

15.2 Chemical Safety Assessment

No

SECTION 16: Other information

Full text of H-Statements

H302

Harmful if swallowed.

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

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Eye Irrit.	: Eye irritation
STOT SE	: Specific target organ toxicity - single exposure
Aquatic Chronic	: Long-term (chronic) aquatic hazard

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road

AIIC - Australian Inventory of Industrial Chemicals

ASTM - American Society for the Testing of Materials

bw - Body weight

CLP - Classification Labelling Packaging Regulation

Regulation (EC) No 1272/2008

CMR - Carcinogen, Mutagen or Reproductive Toxicant

DIN - Standard of the German Institute for Standardisation

DSL - Domestic Substances List (Canada)

ECHA - European Chemicals Agency

EC-Number - European Community number

ECx - Concentration associated with x% response

ELx - Loading rate associated with x% response

EmS - Emergency Schedule

ENCS - Existing and New Chemical Substances (Japan)

ErCx - Concentration associated with x% growth rate response

GHS - Globally Harmonized System

GLP - Good Laboratory Practice

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IC50 - Half maximal inhibitory concentration

ICAO - International Civil Aviation Organization

IECSC - Inventory of Existing Chemical Substances in China

IMDG - International Maritime Dangerous Goods

IMO - International Maritime Organization

ISHL - Industrial Safety and Health Law (Japan)

ISO - International Organisation for Standardization

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KECI - Korea Existing Chemicals Inventory
LC50 - Lethal Concentration to 50 % of a test population
LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)
MARPOL - International Convention for the Prevention of Pollution from Ships
n.o.s. - Not Otherwise Specified
NO(A)EC - No Observed (Adverse) Effect Concentration
NO(A)EL - No Observed (Adverse) Effect Level
NOELR - No Observable Effect Loading Rate
NZIoC - New Zealand Inventory of Chemicals
OECD - Organization for Economic Co-operation and Development
OPPTS - Office of Chemical Safety and Pollution Prevention
PBT - Persistent, Bioaccumulative and Toxic substance
PICCS - Philippines Inventory of Chemicals and Chemical Substances (Q)SAR - (Quantitative) Structure Activity Relationship
REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RID - Regulations concerning the International Carriage of Dangerous Goods by Rail
SADT - Self-Accelerating Decomposition Temperature
SDS - Safety Data Sheet
SVHC - substance of very high concern
TCSI - Taiwan Chemical Substance Inventory
TECI - Thailand Existing Chemicals Inventory
TRGS - Technical Rule for Hazardous Substances
TSCA - Toxic Substances Control Act (United States)
UN - United Nations
vPvB - Very Persistent and Very Bioaccumulative

Further information

Other 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 Material Safety Data Sheet : Information provided by the supplier

Information which has been added, deleted or revised : Updated section / sections:
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.