

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	: 76920/76970
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C ₄₆ H ₅₄ N ₆ O ₈ S ₂
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	: SMILE: 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**Head office**

MOEHS IBÉRICA, S.L.
Roma, 8 - P.I. Cova Solera
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

Manufacturer

MOEHS CANTABRA, S.L.
Pol. Ind. Requejada
39313 Polanco
Spain
T +34 942 131 045 - F +34 942 82 43 98
hse@moehs.com

Manufacturer

MOEHS CATALANA, S.L.
Cesar Martinell i Brunet, 12 A P.I. Rubi Sud
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

1.4. Emergency telephone number

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
------------------	--------------------------------------

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

QUETIAPINE FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

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 which do not result in 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

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation

: Allow affected person to breathe fresh air.

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.

QUETIAPINE FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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.

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. Minimise 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.

QUETIAPINE FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 3 (0.01 - 0.1 mg/m3)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

Personal protective equipment:

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

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

8.2.2.2. Skin protection

Hand protection:

In case of repeated or prolonged contact wear gloves

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

8.2.2.3. Respiratory protection

Respiratory protection:

Dust formation: dust mask

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

QUETIAPINE FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Molecular mass	: 883.1 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 171 – 174 °C
Freezing point	: Not available
Boiling point	: 556.5 °C (@760mmHg)
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: ≈ 290.4 °C (Estimated by ACDLABS)
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: insoluble in water.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 2.93 (Quetiapine base LogP According ALOGPS)
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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

QUETIAPINE FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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.

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

Acute toxicity (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

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : 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

QUETIAPINE FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

QUETIAPINE FUMARATE (111974-72-2)	
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	Not readily biodegradable.
Biodegradation	24 % exposure time:28d Method: OECD Test guideline 301F

12.3. Bioaccumulative potential

QUETIAPINE FUMARATE (111974-72-2)	
Bioconcentration factor (BCF REACH)	1.404 Estimated by BCFWIN v.2.17
Partition coefficient n-octanol/water (Log Pow)	2.93 (Quetiapine base LogP According ALOGPS)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

QUETIAPINE FUMARATE (111974-72-2)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	4.192 Estimated by PCKOWIN v.1.66

12.5. Results of PBT and vPvB assessment

QUETIAPINE FUMARATE (111974-72-2)	
vPvB: not relevant – no registration required	

12.6. Endocrine disrupting properties

No additional information available

12.7. 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 / IMDG / IATA / ADN / RID

14.1. UN number or ID 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

QUETIAPINE FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

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

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

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

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

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. Maritime transport in bulk according to IMO instruments

Not applicable

QUETIAPINE FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

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

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

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen –

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Denmark

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

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

Switzerland

Storage class (LK) : LK 11/13 - Solids

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2

QUETIAPINE FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Full text of H- and EUH-statements:

H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

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.