

# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 21-Nov-2024

Revision Number 1.01

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

### 1.1. Product identifier

**Product Code(s)** CAT 1215  
**Product Name** Quetiapine Fumerate  
**Form** Not applicable

*NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II*

**EC No (EU Index No)** 601-144-2  
**CAS No.** 111974-72-2  
**Chemical name** Quetiapine Hemifumarate  
**Pure substance/mixture** Substance  
**Formula** C42-H50-N6-O4-S2.C4-H4-O4  
**Molecular weight** 883.10

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

**Recommended use** Laboratory use  
**Uses advised against** No information available

### 1.3. Details of the supplier of the safety data sheet

#### Supplier

British Pharmacopoeia Commission  
MHRA  
10 South Colonnade  
Canary Wharf  
London E14 4PU  
United Kingdom

Tel : +44 (0)20 3080 6561  
eMail: bpcrs@mhra.gov.uk



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For further information, please contact

E-mail address bpcrs@mhra.gov.uk

### 1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008	
Europe	112
Austria	No information available
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

## 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)

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Specific target organ toxicity — single exposure	Category 3 - (H336)
Category 3 Narcotic effects	
Chronic aquatic toxicity	Category 2 - (H411)

### 2.2. Label elements

Contains Quetiapine Hemifumarate



**Signal word**  
Warning

### Hazard statements

H302 - Harmful if swallowed  
H319 - Causes serious eye irritation  
H336 - May cause drowsiness or dizziness  
H411 - Toxic to aquatic life with long lasting effects

### Precautionary Statements - EU (§28, 1272/2008)

P264 - Wash face, hands and any exposed skin thoroughly after handling  
P273 - Avoid release to the environment  
P280 - Wear eye protection/ face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P391 - Collect spillage  
P501 - Dispose of contents/ container to an approved waste disposal plant

### 2.3. Other hazards

Toxic to aquatic life.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances

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Quetiapine Hemifumarate	-	-
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### SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Quetiapine Hemifumarate 111974-72-2	100	-	601-144-2	Acute Tox. 4 (H302) Eye Irrit. 2 (H319) STOT SE 3 (H336) Aquatic Chronic 2 (H411)			

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

#### Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air. IF exposed or concerned: Get medical advice/attention.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
<b>Skin contact</b>	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.

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Ingestion	Call a doctor.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).
<b><u>4.2. Most important symptoms and effects, both acute and delayed</u></b>	
Symptoms	Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.
<b><u>4.3. Indication of any immediate medical attention and special treatment needed</u></b>	
Note to doctors	Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.

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

Specific hazards arising from the chemical	No information available.
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### 5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## SECTION 6: Accidental release measures

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

Personal precautions	Avoid contact with skin, eyes or clothing.
Other information	Refer to protective measures listed in Sections 7 and 8.

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**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** See Section 12 for additional Ecological Information.

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

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Advice on safe handling** Ensure adequate ventilation. Avoid breathing vapours or mists. In case of insufficient ventilation, wear suitable respiratory equipment.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

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

**Storage Conditions** Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

### 7.3. Specific end use(s)

**Risk Management Methods (RMM)** The information required is contained in this Safety Data Sheet.

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## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

#### Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

#### Derived No Effect Level (DNEL)

No information available.

#### Predicted No Effect Concentration (PNEC)

No information available.

### 8.2. Exposure controls

#### Personal protective equipment

##### Eye/face protection

Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.

##### Hand protection

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear suitable gloves.

Gloves			
Duration of contact	PPE - Glove material	Glove thickness	Break through time
	Wear protective butyl rubber gloves		
	Wear protective nitrile rubber gloves	0.11 mm	480 minutes

##### Skin and body protection

Wear suitable protective clothing.

##### Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

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<b>General hygiene considerations</b>	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.
<b>Environmental exposure controls</b>	Do not allow into any sewer, on the ground or into any body of water.

## SECTION 9: Physical and chemical properties

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

<b>Physical state</b>	Solid
<b>Appearance</b>	Solid
<b>Colour</b>	white
<b>Odour</b>	No information available.
<b>Odour threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>Melting point / freezing point</b>	172 °C	None known
<b>Initial boiling point and boiling range</b>	No data available	None known
<b>Flammability</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>pH</b>	No data available	None known
<b>pH (as aqueous solution)</b>	No data available	No information available
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Water solubility</b>	No data available	None known
<b>Solubility(ies)</b>	Chloroform, Methanol	
<b>Partition coefficient</b>	No data available	None known
<b>Vapour pressure</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Bulk density</b>	No data available	
<b>Liquid Density</b>	No data available	
<b>Relative vapour density</b>	No data available	None known
<b>Particle characteristics</b>		



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Particle Size No information available  
Particle Size Distribution No information available

### 9.2. Other information

Molecular weight 883.10  
Molecular formula C42-H50-N6-O4-S2.C4-H4-O4

9.2.1. Information with regards to physical hazard classes  
Not applicable

9.2.2. Other safety characteristics  
No information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactivity No information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

#### Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

### 10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

### 10.5. Incompatible materials

Incompatible materials None known based on information supplied.

### 10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

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## SECTION 11: Toxicological information

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

#### Information on likely routes of exposure

##### Product Information

Inhalation	May cause drowsiness or dizziness.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Harmful if swallowed. (based on components).

#### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.
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#### Numerical measures of toxicity

##### Acute toxicity

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitisation	No information available.

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**Germ cell mutagenicity** No information available.

**Carcinogenicity** No information available.

**Reproductive toxicity** No information available.

**STOT - single exposure** May cause drowsiness or dizziness.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

#### 11.2. Information on other hazards

##### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

##### 11.2.2. Other information

**Other adverse effects** No information available.

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Ecotoxicity** Toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Quetiapine Hemifumarate	EC50: 8.03 mg/L (96h, Algae)	LC50: 19.3µg/L (96h, Fish)	-	-

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#### 12.2. Persistence and degradability

Persistence and degradability No information available.

#### 12.3. Bioaccumulative potential

Bioaccumulation No information available.

#### 12.4. Mobility in soil

Mobility in soil No information available.

#### 12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

#### 12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

#### 12.7. Other adverse effects

No information available.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

### SECTION 14: Transport information

#### IATA

14.1 UN number or ID number

UN3077

14.2 UN proper shipping name

Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate)

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14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate), 9, III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	A97, A158, A179, A197, A215
ERG Code	9L

### IMDG

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate), 9, III, Marine pollutant
14.5 Marine pollutant	P
Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	274, 335, 966, 967, 969
EmS-No.	F-A, S-F No information available
14.7 Maritime transport in bulk according to IMO instruments	No information available

### RID

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate), 9, III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	274, 335, 375, 601
Classification code	M7

### ADR

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate), 9, III, (-)

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14.5 Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	274, 335, 601, 375
Classification code	M7
Tunnel restriction code	(-)

## SECTION 15: Regulatory information

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

#### National regulations

##### Germany

Water hazard class (WGK) strongly hazardous to water (WGK 3)

##### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

#### Persistent Organic Pollutants

Not applicable

#### Dangerous substance category per Seveso Directive (2012/18/EU)

E2 - Hazardous to the Aquatic Environment in Category Chronic 2

#### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

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## International Inventories

### TSCA

LGC has not confirmed that the chemical substances in this product are on the TSCA Inventory, and LGC is distributing this product solely for use either in applications statutorily exempt from TSCA and regulated under other laws (e.g., FFDCA, FIFRA) or in research and development activities in accordance with the TSCA Inventory R&D exemption provided at 40 CFR 720.36. It is the end-user's responsibility to understand and follow the requirements that apply to its use of this product.

### DSL/NDSL

### EINECS/ELINCS

### ENCS

### IECSC

### KECL

### PICCS

### AIIC

Contact supplier for inventory compliance status

Contact supplier for inventory compliance status

Contact supplier for inventory compliance status

Contact supplier for inventory compliance status

Contact supplier for inventory compliance status

Contact supplier for inventory compliance status

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## Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

### Chemical Safety Report

A Chemical Safety Assessment is not required for this substance

## SECTION 16: Other information

### Key or legend to abbreviations and acronyms used in the safety data sheet

### Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

H319 - Causes serious eye irritation

H336 - May cause drowsiness or dizziness

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H411 - Toxic to aquatic life with long lasting effects

### Legend

SVHC: Substances of Very High Concern for Authorisation:

### Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average)  
Ceiling Maximum limit value

STEL  
Sk\*

STEL (Short Term Exposure Limit)  
Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Chronic aquatic toxicity	Calculation method
Acute aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGL(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification



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Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme  
Organisation for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

Revision date 21-Nov-2024

Reason for revision Chemical Safety Report Gloves Material

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

### Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

**End of Safety Data Sheet**