

British Pharmacopoeia

Quality standards

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

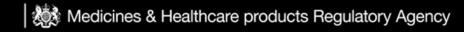
Revision date 21-Nov-2024

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
	nber is given for this substance because it is under the threshold in REACH Article istration 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 sa	fety 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	

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		

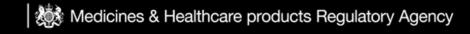
SECTION 2: Hazards identification

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

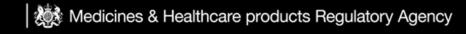
P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

Toxic to aquatic life.

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

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





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Quetiapine Hemifumarate

SECTION 3: Composition/information on ingredients

3.1 Substances

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

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

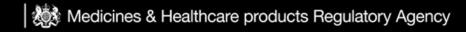
Acute Toxicity Estimate No information available

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

SECTION 4: First aid measures	

4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.	
Inhalation	Remove to fresh air. IF exposed or concerned: Get medical advice/attention.	
Eye contact	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.	
Skin contact	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)	
4.2. Most important symptoms and e	ffects, both acute and delayed	
Symptoms	Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.	
4.3. Indication of any immediate medical attention and special treatment needed		
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.	

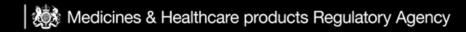
5.3. Advice for firefighters

Special protective equipment and	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.
precautions for fire-fighters	Use personal protection equipment.

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 contai	nment 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	

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	No information available.
(PNEC)	

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 0.11 m rubber gloves		0.11 mm	480 minutes
Skin and body protection	Wear suitable protective clothing.		
Description and the sting			

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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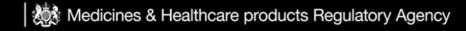
CAT 1215 - Quetiapine Fumerate

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.
Environmental exposure controls	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

9.1. Information on basic physical a	nd chemical properties	
Physical state	Solid	
Appearance	Solid	
Colour	white	
Odour	No information available.	
Odour threshold	No information available	
Property	Values	Remarks • Method
Melting point / freezing point	172 °C	None known
Initial boiling point and boiling rang		None known
Flammability	No data available	None known
Flammability Limit in Air	NU Uala avaliable	None known
-	No data available	NOTE KIOWI
Upper flammability or explosive limits	No data avaliable	
Lower flammability or explosive	No data available	
limits		
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	Chloroform, Methanol	
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		





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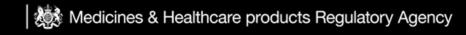
Particle Size	No information available
Particle Size Distribution	No information available
<u>9.2. Other information</u> Molecular weight Molecular formula	883.10 C42-H50-N6-O4-S2.C4-H4-O4

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 No information available. Reactivity 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

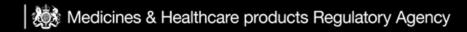
Information on likely routes of exposure

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.	
Numerical measures of toxicity		
Acute toxicity		
Delayed and immediate effects as v	vell 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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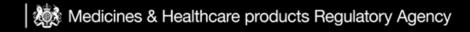
Germ cell mutagenicity	No information available.	
Carcinogenicity	No information available.	
Reproductive toxicity	No information available.	
STOT - single exposure	May cause drowsiness or dizziness.	
STOT - repeated exposure	No information available.	
Aspiration hazard	No information available.	
11.2. 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	Crustacea
			microorganisms	
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

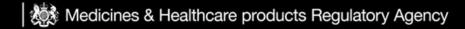
13.1. Waste treatment methods

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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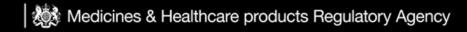
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 14.3 Transport hazard class(es) 14.4 Packing group Description 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions ERG Code 	9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate), 9, III Yes
	A97, A158, A179, A197, A215 9L
 IMDG 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group Description 14.5 Marine pollutant Environmental hazards 14.6 Special precautions for user Special Provisions EmS-No. 14.7 Maritime transport in bulk according to IMO instruments 	UN3077 Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate), 9, III, Marine pollutant P Yes 274, 335, 966, 967, 969 F-A, S-F No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group Description14.5Environmental hazards14.6Special precautions for user Special Provisions Classification code	UN3077 Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate), 9, III Yes 274, 335, 375, 601 M7
ADR 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group Description	UN3077 Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate) 9 III UN3077, Environmentally hazardous substances, solid, n.o.s. (Quetiapine Hemifumarate), 9, III, (-)





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

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

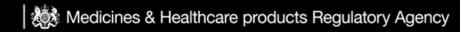
Not applicable

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	Contact supplier for inventory compliance status	
EINECS/ELINCS	Contact supplier for inventory compliance status	
ENCS	Contact supplier for inventory compliance status	
IECSC	Contact supplier for inventory compliance status	
KECL	Contact supplier for inventory compliance status	
PICCS	Contact supplier for inventory compliance status	
AIIC	Contact supplier for inventory compliance status	
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		
15.2. Chemical safety assessment	-	
Chemical Safety Report	A Chemical Safety Assessment is not required for this substance	

SECTION 16: Other information

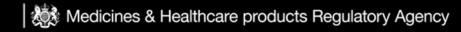
Key or legend to abbreviations and acronyms used in the safety data sheet

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:

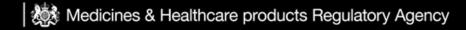
Legend Section 8: Exposure controls/personal protection

TWĂ	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	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 heldresponsible 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