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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

#### SEROQUEL TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD      Emergency Telephone  
PO Box 131      +44 (0) 1235 239 670  
66 Talavera Rd, North Ryde  
NSW 2113  
AUSTRALIA  
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

#### Alternative Names

Quetiapine fumarate tablets  
Also valid for Seroquel XR Tablets  
CAS No. : Not applicable

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

Use of the Substance/Mixture : Treatment of acute and chronic psychoses, including schizophrenia

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## SECTION 2. HAZARDS IDENTIFICATION


#### GHS Classification

Serious eye damage/eye irritation : Category 1

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H318 Causes serious eye damage.  
H401 Toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.  
P280 Wear eye protection/ face protection.  
**Response:**  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with

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water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.  
 P391 Collect spillage.

**Disposal:**

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

**Other hazards which do not result in classification**

May cause skin irritation in sensitive individuals.

See Section 11.

The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Celluloses	9004-34-6	30 -55
Quetiapine fumarate	111974-72-2	11 -52
Magnesium stearate	557-04-0	1 -2

**SECTION 4. FIRST AID MEASURES**

- If inhaled : Remove patient from exposure.  
Obtain medical attention.
- In case of skin contact : Remove contaminated clothing.  
Wash skin immediately with water.  
Obtain medical attention.
- In case of eye contact : Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes.  
Obtain immediate medical attention.  
Continue irrigation until medical attention can be obtained.
- If swallowed : Wash out mouth with water.  
Do NOT induce vomiting as a First-Aid measure.  
Obtain medical attention.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11  
Causes serious eye damage.
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.  
For further detail consult the prescribing information.

**SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing media : water spray, foam, dry powder or CO2.

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- Unsuitable extinguishing media : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
- Specific hazards during firefighting : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.  
Prevent fire extinguishing water from contaminating surface water or the ground water system.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Avoid dispersal of dust in the air.  
Ensure suitable personal protection during removal of spillages.  
See Section 8.
- Environmental precautions : Do not allow to enter drains, sewers or watercourses.  
Collect spillage.
- Methods and materials for containment and cleaning up : Transfer spilled tablets to a suitable container for disposal.  
Wash the spillage area with water.  
Avoid release to the environment.  
  
See section 13.

## SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid contact with skin and eyes.  
Wash hands after use.  
Minimize dust generation and accumulation.  
The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.
- Conditions for safe storage : Keep container tightly closed.
- Recommended storage temperature : < 30 °C

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Celluloses	9004-34-6	TWA	10 mg/m <sup>3</sup>	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m <sup>3</sup>	ACGIH
Quetiapine fumarate	111974-72-2	TWA	0.1 mg/m <sup>3</sup>	COM; HYG
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	AU OEL

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	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA (Inhalable fraction)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable fraction)	3 mg/m <sup>3</sup>	ACGIH

**Engineering measures** : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.  
See Section 6 for environmental precautions.

## Personal protective equipment

**Respiratory protection** : Use a negative pressure air purifying respirator (half face mask) with filter class P3 if the risk assessment does not support the selection of other protection.

**Eye protection** : Use goggles to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

**Skin and body protection** : Use protective clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

**Protective measures** : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : film-coated tablets

Colour : Seroquel, 25 mg - peach; 50/200/300 mg - white;  
100/150/400 mg - yellow.  
  
Seroquel XR, 50mg - peach; 150mg-white; 200mg - yellow;  
300mg - pale yellow; 400mg - white

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/range : No data available

Initial boiling point and boiling range : Not applicable

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Solubility(ies)  
Water solubility : No data available  
  
Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

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Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	Not applicable

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	None known.
Hazardous decomposition products	:	No hazardous decomposition products are known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1 Acute toxicity

Not classified based on available information.

#### **Product:**

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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#### **Components:**

##### **Quetiapine fumarate:**

Acute oral toxicity	:	LD50 Oral (Rat): 2,000 mg/kg Assessment: The component/mixture is moderately toxic after single ingestion.
Acute inhalation toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)
Acute dermal toxicity	:	Remarks: No information available.

### 11.2 Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

##### **Quetiapine fumarate:**

Result	:	Mild skin irritation
Remarks	:	Mild skin irritant in vivo. May cause skin irritation in sensitive individuals.

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### 11.3 Serious eye damage/eye irritation

Causes serious eye damage.

#### Components:

##### Quetiapine fumarate:

Result	:	Irreversible effects on the eye
Remarks	:	Severe eye irritant in vivo.

### 11.4 Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Quetiapine fumarate:

Remarks	:	It is not a skin sensitiser in vivo.
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#### Chronic toxicity

### 11.5 Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Quetiapine fumarate:

Germ cell mutagenicity - Assessment	:	The substance is not considered to be genotoxic.
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### 11.6 Carcinogenicity

Not classified based on available information.

#### Components:

##### Quetiapine fumarate:

Carcinogenicity - Assessment	:	Studies in animals have shown that repeated doses produce tumours in rats and mice., It is unlikely to present a carcinogenic hazard to man.
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### 11.7 Reproductive toxicity

Not classified based on available information.

#### Components:

##### Quetiapine fumarate:

Reproductive toxicity - Assessment	:	A study in animals has shown that high doses cause adverse effects on fertility.
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### 11.8 STOT - single exposure

Not classified based on available information.

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**Components:****Quetiapine fumarate:**

Exposure routes : Oral, Inhalation  
 Target Organs : Heart, Central nervous system  
 Remarks : May cause sedation and dizziness  
 May cause tachycardia and hypotension.

**11.9 STOT - repeated exposure**

Not classified based on available information.

**Components:****Quetiapine fumarate:**

Remarks : May cause effects as described under single exposure.(STOT)

**11.10 Aspiration toxicity**

Not classified based on available information.

**Components:****Quetiapine fumarate:**

No information available.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Product:****Ecotoxicology Assessment**

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

**Components:****Quetiapine fumarate:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 22.0 mg/l  
 Exposure time: 96 h  
 Test Type: static test

NOEC (Oncorhynchus mykiss (rainbow trout)): 1.0 mg/l  
 Exposure time: 96 h  
 Test Type: static test

LC50 (Lepomis macrochirus (Bluegill sunfish)): 19.3 mg/l  
 Exposure time: 96 h  
 Test Type: static test

NOEC (Lepomis macrochirus (Bluegill sunfish)): 1.8 mg/l  
 Exposure time: 96 h  
 Test Type: static test

Toxicity to algae/aquatic : EC50 (Selenastrum capricornutum (green algae)): 8.03 mg/l



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- plants
- Exposure time: 96 h  
Test Type: growth rate
- NOEC (*Selenastrum capricornutum* (green algae)): 2.5 mg/l  
Exposure time: 14 d  
Test Type: growth rate
- NOEC (*Microcystis aeruginosa* (blue-green algae)): 32 mg/l  
Exposure time: 21 d  
Test Type: growth rate
- Toxicity to fish (Chronic toxicity) : NOEC (*Pimephales promelas* (fathead minnow)): 0.1 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 18 mg/l  
Exposure time: 21 d  
Test Type: Reproduction Test
- M-Factor (Chronic aquatic toxicity) : 1
- Toxicity to microorganisms : NOEC (activated sludge): > 100 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Ecotoxicology Assessment**

- Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

**Persistence and degradability****Components:****Quetiapine fumarate:**

- Biodegradability : aerobic  
Result: Not rapidly biodegradable  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F
- anaerobic  
Result: Not rapidly biodegradable  
Biodegradation: 0 %  
Exposure time: 57 d

**Bioaccumulative potential****Components:****Quetiapine fumarate:**

- Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

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## Mobility in soil

### Components:

#### Quetiapine fumarate:

Mobility : Remarks: Water solubility  $\geq$  1 mg/l.

Distribution among environmental compartments : Remarks: No information available.

#### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Disposal should be in accordance with local, state or national legislation.  
Waste, even small quantities, should never be poured down drains, sewers or water courses.  
Dispose of contents/ container to an approved incineration plant.

Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.

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## SECTION 14. TRANSPORT INFORMATION

### ICAO/IATA

UN No. : 3077  
Proper Shipping Name : Environmentally hazardous substance, solid, n.o.s. (QUETIAPINE FUMARATE)  
Class : 9  
Packing Group : III  
Environmental hazards : Environmentally hazardous

### IMO/MDG

UN No. : 3077  
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (QUETIAPINE FUMARATE)  
Class : 9  
Packing Group : III  
Marine pollutant : Marine pollutant

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## ADR

UN No. : 3077  
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(QUETIAPINE FUMARATE)  
Class : 9  
Label(s) : 9  
Packing Group : III  
Environmental hazards : Environmentally hazardous

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## SECTION 15. REGULATORY INFORMATION

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

In order to comply with legal duties it is necessary to consult local and national legislation.

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

### **The components of this product are reported in the following inventories:**

TCSI : Not listed  
TSCA : Substance(s) not listed on TSCA inventory  
AICS : Not listed  
DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
Quetiapine fumarate  
ENCS : Not listed  
ISHL : Not listed  
KECI : Not listed  
IECSC : Not listed  
CHINV : Not in compliance with the inventory  
REACH : Not in compliance with the inventory  
TRINV : Not in compliance with the inventory

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**SECTION 16. OTHER INFORMATION****Further information**

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Other information : Minor changes:  
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Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average

AU OEL / TWA : Exposure standard - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CHINV - China Inventory; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM - In-house occupational exposure limit; CPR - Controlled Products Regulations; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HYG - Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; Sen - Capable of causing respiratory sensitization; Sk - Can be absorbed through skin, thus contributing to systemic effects; STEL - Short-term exposure limit 15-minutes time-weighted average; TLV - Threshold Limit Value (ACGIH); TLV-C - Threshold Limit Value Ceiling limit (ACGIH); TRINV - Turkey Inventory; TSCA - Toxic Substances Control Act (United States); TWA - Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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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.

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