

Version	Revision Date:	SDS Number:	Date of last issue: 19.12.2017
4.0	13.08.2019	1010	Date of first issue: 19.12.2017

---

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

## SEROQUEL TABLETS

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

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
------------------------------	---

---

## 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	: <b>Prevention:</b> P273 Avoid release to the environment. P280 Wear eye protection/ face protection. <b>Response:</b> P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with
--------------------------	---

# SAFETY DATA SHEET



Version 4.0      Revision Date: 13.08.2019      SDS Number: 1010      Date of last issue: 19.12.2017  
Date of first issue: 19.12.2017

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.
- Unsuitable extinguishing : Avoid high pressure media which could cause the formation of

Version 4.0      Revision Date: 13.08.2019      SDS Number: 1010      Date of last issue: 19.12.2017  
 Date of first issue: 19.12.2017

media      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
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			

# SAFETY DATA SHEET



Version 4.0      Revision Date: 13.08.2019      SDS Number: 1010      Date of last issue: 19.12.2017  
Date of first issue: 19.12.2017

		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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : film-coated tablets

# SAFETY DATA SHEET



Version 4.0      Revision Date: 13.08.2019      SDS Number: 1010      Date of last issue: 19.12.2017  
Date of first issue: 19.12.2017

---

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  
Viscosity, dynamic : Not applicable  
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : Not applicable





Version 4.0      Revision Date: 13.08.2019      SDS Number: 1010      Date of last issue: 19.12.2017  
Date of first issue: 19.12.2017

---

**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.

---

**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 : EC50 (Selenastrum capricornutum (green algae)): 8.03 mg/l  
Test Type: growth rate

NOEC (Selenastrum capricornutum (green algae)): 2.5 mg/l  
Test Type: growth rate

NOEC (Microcystis aeruginosa (blue-green algae)): 32 mg/l  
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



# SAFETY DATA SHEET



Version 4.0      Revision Date: 13.08.2019      SDS Number: 1010      Date of last issue: 19.12.2017  
Date of first issue: 19.12.2017

---

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.

## 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

Version            Revision Date:            SDS Number:            Date of last issue: 19.12.2017  
4.0                13.08.2019                1010                    Date of first issue: 19.12.2017

---

**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.
- 

**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/IMDG**

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

**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



