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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
 PO Box 131
 Alma Road, 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

Acute aquatic toxicity : Category 2

Chronic aquatic toxicity : 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 water for several minutes. Remove contact lenses, if present

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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.

Hazardous components which must be listed on the label:

Quetiapine fumarate

Other hazards which do not result in classification

May cause skin irritation in sensitive individuals.

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

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Quetiapine fumarate	111974-72-2	11 -52

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
Quetiapine fumarate	111974-72-2	TWA	0.1 mg/m ³	COM; HYG

- 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

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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
- 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

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Odour Threshold : No data available

pH : No data available

Melting point/range : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

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 : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)

 Water solubility : soluble

 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 : No data available

 Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.

Chemical stability : Stable under normal conditions.

Possibility of hazardous : None known.

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reactions

Conditions to avoid : No conditions producing hazardous situations known.

Incompatible materials : None known.

Hazardous decomposition products : No hazardous decomposition products are known.

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

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: May cause skin irritation in sensitive individuals.

11.3 Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Quetiapine fumarate:

Result: Irreversible effects on the eye
Remarks: Severe/very severe irritant to rabbit eyes.

11.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

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Respiratory sensitisation

Not classified based on available information.

Components:

Quetiapine fumarate:

Remarks: It is not a skin sensitiser in animal tests.

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.

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.

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.

11.8 STOT - single exposure

Not classified based on available information.

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.

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Components:**Quetiapine fumarate:**

Exposure routes: Oral

Target Organs: Central nervous system, Eyes

Remarks: Chronic ingestion studies in animals have shown that repeated doses produce adverse effects such as cataracts and seizures in dogs.

11.10 Aspiration toxicity

Not classified based on available information.

Components:**Quetiapine fumarate:**

No information available.

Further information**Product:**

Remarks: This health hazard assessment is based on a consideration of the composition of this product.

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

M-Factor (Chronic aquatic toxicity) : 1

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 testNOEC (Oncorhynchus mykiss (rainbow trout)): 1.0 mg/l
Exposure time: 96 H
Test Type: static testLC50 (Lepomis macrochirus (Bluegill sunfish)): 19.3 mg/l
Exposure time: 96 H
Test Type: static testNOEC (Lepomis macrochirus (Bluegill sunfish)): 1.8 mg/l
Exposure time: 96 H
Test Type: static test

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- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 10 - 100 mg/l
Exposure time: 48 H
- Toxicity to algae : EC50 (Selenastrum capricornutum (green algae)): 8.03 mg/l
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: 2 %
Method: OECD Test Guideline 301C

aerobic
Result: Not rapidly biodegradable
Biodegradation: 24 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

Quetiapine fumarate:

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

Mobility in soil

Components:

Quetiapine fumarate:

Mobility : Remarks: Water solubility ≥ 1 mg/l.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

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

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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

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:

REACH : Not listed
DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
Quetiapine fumarate : 111974-72-2
AICS : Not listed
ENCS : Not listed
ISHL : Not listed
IECSC : Not listed
TCSI : Not listed
TSCA : Not On TSCA Inventory

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SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

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; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; 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; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; 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; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; 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; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (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; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); 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

Further information

Revision Date	:	19.12.2017
Other information	:	The Safety Data Sheet has been updated to the SAP EH&S Standard template., This update affects all Sections of the Safety Data Sheet., New significant SHE information:., 2. New classification, 11. New classification, Minor changes:., 2, 4, 6, 11, 12, 13
Date format	:	dd.mm.yyyy

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