



# MATERIAL SAFETY DATA SHEET

Revision date: 09-Jan-2012

Version: 1.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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### Material Name: Quetiapine Tablets

Trade Name:	Not applicable
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product used as antipsychotic

## 2. HAZARDS IDENTIFICATION

**Appearance:** Tablets, varying in color depending on strength  
**Signal Word:** DANGER

**Statement of Hazard:** Causes eye irritation.  
May damage the unborn child.  
May cause harm to breastfed babies.  
Toxic to aquatic life with long lasting effects.

**Additional Hazard Information:**  
**Short Term:** Accidental ingestion may cause effects similar to those seen in clinical use.  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus and thyroid.

**Known Clinical Effects:** Adverse effects associated with therapeutic use include dizziness, sleepiness (somnolence) dry mouth, constipation, difficult digestion (dyspepsia), low blood pressure on standing (orthostatic hypotension), increased heart rate (tachycardia). May cause harm to breastfed babies.

**EU Classification**  
**EU Indication of danger:** Toxic to Reproduction: Category 2  
Dangerous for the Environment

**EU Hazard Symbols:**



**EU Risk Phrases:**  
R41 - Risk of serious damage to eyes.  
R61 - May cause harm to the unborn child.  
R64 - May cause harm to breastfed babies.

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## 2. HAZARDS IDENTIFICATION

### Australian Hazard Classification (NOHSC):

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Silica colloidal, Ph. Eur.	112945-52-5	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Quetiapine fumarate	111974-72-2	Not Listed	Repr. Cat.2;R61-R64;Xi,R41;N,R51/53	46

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	*
Dibasic calcium phosphate, dihydrate USP	7789-77-7	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*

### Additional Information:

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

## 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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### 5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

- Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
- Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
- Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

- General Handling:** Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
- Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Silica colloidal, Ph. Eur.	
Austria OEL - MAKs	4 mg/m <sup>3</sup>
Microcrystalline cellulose	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

**Talc (non-asbestiform)**

ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	2.5 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 fiber/cm <sup>3</sup>
	6.0 mg/m <sup>3</sup>
	3.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	2.0 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Denmark OEL - TWA	0.3 fiber/cm <sup>3</sup>
Finland OEL - TWA	0.5 fiber/cm <sup>3</sup>
	5 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	0.8 mg/m <sup>3</sup>
Lithuania OEL - TWA	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.25 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m <sup>3</sup>
	1.0 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Romania OEL - TWA	2 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Spain OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>

**Magnesium stearate**

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

**Quetiapine fumarate**

**Pfizer Occupational Exposure Band (OEB):** OEB 3 (control exposure to the range of >10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

**Engineering Controls:**

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Environmental Exposure Controls:**

Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Tablets	<b>Color:</b>	Various
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Quetiapine fumarate

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

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### 11. TOXICOLOGICAL INFORMATION

#### Quetiapine fumarate

Embryo / Fetal Development	Rat	Oral 25 mg/kg/day	NOEL	Not teratogenic, Embryotoxicity, Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral 25 mg/kg/day	NOEL	Not Teratogenic, Embryotoxicity, Fetotoxicity
Peri-/Postnatal Development	Rat	Oral 20 mg/kg/day	NOEL	No effects at maximum dose
Reproductive & Fertility	Rat	Oral 25 mg/kg/day	NOEL	Negative

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Quetiapine fumarate

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Positive
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Quetiapine fumarate

2 Year(s)	Rat	Oral 250 mg/kg/day	LOAEL	Thyroid, Tumors, Mammary gland
2 Year(s)	Mouse	Oral 250 mg/kg/day	LOAEL	Thyroid, Tumors

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Povidone

IARC: Group 3 (Not Classifiable)

#### Silica colloidal, Ph. Eur.

IARC: Group 3 (Not Classifiable)

#### Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

**Mobility, Persistence and Degradability:** Not readily biodegradable ( 24 % after 28 days).

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### Quetiapine fumarate

Green algae	EC50	3.59 mg/L		
<i>Daphnia magna</i> (Water Flea)	EC50	48 Hours	> 32 mg/L	
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50	96 Hours	22 mg/L	

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### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

**EU Indication of danger:** Toxic to Reproduction: Category 2  
Dangerous for the Environment

**EU Risk Phrases:**  
R41 - Risk of serious damage to eyes.  
R61 - May cause harm to the unborn child.  
R64 - May cause harm to breastfed babies.  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
S53 - Avoid exposure - obtain special instructions before use.  
S57 - Use appropriate containment to avoid environmental contamination.

**OSHA Label:**  
DANGER  
Causes eye irritation.  
May damage the unborn child.  
May cause harm to breastfed babies.  
Toxic to aquatic life with long lasting effects.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A



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### 15. REGULATORY INFORMATION

<b>Silica colloidal, Ph. Eur.</b>	
Australia (AICS):	Present
<b>Sodium starch glycolate</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
<b>Microcrystalline cellulose</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9
<b>Dibasic calcium phosphate, dihydrate USP</b>	
Australia (AICS):	Present
<b>Water, purified</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
<b>Talc (non-asbestiform)</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9
<b>Magnesium stearate</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3
<b>Lactose NF, monohydrate</b>	
Australia (AICS):	Present
<b>Povidone</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R41 - Risk of serious damage to eyes.

R61 - May cause harm to the unborn child.

R64 - May cause harm to breastfed babies.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients.



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**Prepared by:**

Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**