



# Safety Data Sheet

## Quetiapine Assay Kit

According to Regulation (EC) No. 1907/2006  
(REACH) with its amendments Regulations (EU)  
2015/830 and (EU) 2020/878

Date of issue: 2023-08-01



### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Product Form : Mixture  
Product Name : Psychiatry Quetiapine Assay Kit  
Product Code : C82917

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

Industrial/Professional Use : For Professional Use Only  
Use of the Substance/Mixture : In Vitro Diagnostic Medical Device

#### 1.3 Details of the supplier of the safety data sheet

<b>Manufacturer</b>	<b>European Authorized Representative</b>
Saladax Biomedical, Inc. 116 Research Dr. Bethlehem, PA.18015 Tel. 610-419-6731 techsupport@saladax.com www.saladax.com	EMERGO EUROPE Westervoortsedijk 60, 6827 AT Arnhem The Netherlands T +31 (0) 70 345 8570

#### 1.4 Emergency telephone number

Emergency Number : CHEMTREC 1-800-424-9300 (US or Canada);1-703-527-3887 (International)

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

This substance is classified as not hazardous according to Regulation (EC) No. 1272/2008 [CLP].

#### 2.2 Label elements

##### Labeling according to Regulation (EC) No. 1272/2008 [CLP]

According to Regulation (EC) No. 1272/2008 [CLP], this product does not require labeling.

#### 2.3 Other hazards

No other hazards identified

### SECTION 3: Composition/information on ingredients

#### 3.1 Substance

Not applicable

#### 3.2 Mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No. 1272/2008 [CLP].

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

General	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if breathing is irregular or stopped.
Skin Contact	: Remove/take off immediately all contaminated clothing. Rinse skin with water/shower. Wash with plenty of soap and water. Wash contaminated clothing before reuse. Call a POISON CENTER or doctor/physician in case of skin reaction.
Eye Contact	: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for 10-15 minutes. Obtain medical attention if pain, blinking or redness persists.
Ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER or doctor/physician if you feel unwell.

#### 4.2 Most important symptoms and effects, both acute and delayed

No known symptoms or effects identified

#### 4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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#### SECTION 5: Firefighting measures

##### 5.1 Extinguishing media

Suitable Extinguishing Media : The product itself does not burn. Coordinate fire-fighting measures to the fire surroundings.  
 Unsuitable Extinguishing Media : No restrictions.

##### 5.2 Special hazards arising from the substance or mixture

No specific hazards.

##### 5.3 Advice for firefighters

No specific advice for firefighters.

#### SECTION 6: Accidental release measures

##### 6.1 Personal precautions, protective equipment and emergency procedures

General Measures : Clean spills immediately with absorbent material and rinse the area with water.

##### 6.1.1 For non-emergency personnel

Emergency Procedures : Evacuate unnecessary personnel.

##### 6.1.2 For emergency responders

Personal Protective Equipment : Refer to Section 8 of this SDS for appropriate personal protective equipment.  
 Emergency Procedures : No specific emergency procedures.

##### 6.2 Environmental precautions

No specific environmental precautions

##### 6.3 Methods and material for containment and cleaning up

Clean spills with absorbent material. Rinse spill area with water.

##### 6.4 Reference to other sections

Refer to sections 8 and 13.

#### SECTION 7: Handling and storage

##### 7.1 Precautions for safe handling

Protective Measures : Wear gloves when handling.  
 General Occupational Hygiene : Do not eat, drink, or smoke when using this product. Wash hands thoroughly after handling.

##### 7.2 Conditions for safe storage, including any incompatibilities

Storage Conditions : Store refrigerated at 2-8 °C.

##### 7.3 Specific end use(s)

For *in vitro* diagnostic use only

#### SECTION 8: Exposure controls/personal protection

##### 8.1 Control parameters

Does not contain substances above concentration limits requiring an occupational exposure limit.

##### 8.2 Exposure controls

Personal Protective Equipment : Avoid all unnecessary exposure. Wear safety glasses, gloves, protective clothing.  
 Hand Protection : Wear protective gloves.  
 Eye Protection : Wear chemical goggles or safety glasses.  
 Respiratory Protection : No respiratory protection necessary.  
 Other Information : Do not eat, drink, or smoke during use.

#### SECTION 9: Physical and chemical properties

##### 9.1 Information on basic physical and chemical properties

Physical State : Liquid  
 Color : R1 : Clear, yellow to orange color ; R2 : Opaque white liquid  
 Odor : Little or no odor  
 Odor Threshold : No data available  
 pH : R1 : 7.0; R2 : 7.5  
 Melting Point : 0 °C  
 Boiling Point : 100 °C  
 Flash Point : Not applicable – Aqueous Solution



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Auto-ignition Temperature	: Not applicable – Aqueous Solution
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: 24 mmHg
Relative Vapor Density at 20 °C	: No data available
Relative Density	: 1 g/cm <sup>3</sup>
Solubility	: Miscible in water
Viscosity, Kinematic	: No data available

#### 9.2 Other Information

No other relevant information

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Stable under normal conditions.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

No hazardous reactions.

#### 10.4 Conditions to avoid

Stable under normal conditions.

#### 10.5 Incompatible materials

No incompatible materials.

#### 10.6 Hazardous decomposition products

No hazardous decomposition products.

### SECTION 11: Toxicological information

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute Toxicity	: Not classified (Based on available data, the classification criteria are not met)
Skin Corrosion / Irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious Eye Damage / Irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or Skin Sensitization	: Not classified (Based on available data, the classification criteria are not met)
Germ Cell Mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive Toxicity	: Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity Single Exposure	: Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity Repeated Exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration Hazard	: Not classified (Based on available data, the classification criteria are not met)

#### 11.2 Information on other hazards

No other hazards identified

### SECTION 12: Ecological information

#### 12.1 Toxicity

No data available

#### 12.2 Persistence and degradability

No data available

#### 12.3 Bioaccumulative potential

No data available

#### 12.4 Mobility in soil

No data available



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#### 12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

#### 12.6 Endocrine disrupting properties

Contains no endocrine disrupting components above cutoff limits

#### 12.7 Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

Waste Disposal Recommendations : Dispose according to local / national regulations.

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

#### 14.1 UN number

Not applicable

#### 14.2 UN proper shipping name

Not applicable

#### 14.3 Transport hazard class(es)

Not classified (Based on available data, the classification criteria are not met)

#### 14.4 Packing group

Not classified (Based on available data, the classification criteria are not met)

#### 14.5 Environmental hazards

Dangerous to the environment : No  
 Marine Pollutant : No  
 Other Information : No supplementary information available

#### 14.6 Special precautions for user

No special precautions required

#### 14.7 Maritime transport in bulk according to IMO instruments

Not applicable

### SECTION 15: Regulatory information

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

##### 15.1.1 EU-Regulations

Contains no REACH substances with Annex XVII restrictions  
 Contains no substance on the REACH candidate list  
 Contains no REACH Annex XIV substances

##### 15.1.2 National regulations

No additional information available

#### 15.2 Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

Descriptions of document changes available upon request

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SDS EU (REACH Annex II)

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