



# Safety Data Sheet

## Clozapine 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 Clozapine Assay Kit  
 Product Code : C82914

#### 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

Manufacturer	European Authorized Representative
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 : 6.7; R2 : 7.5

Melting Point : 0 °C

Boiling Point : 100 °C



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Flash Point	: Not applicable – Aqueous Solution
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

### 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

Distributed by

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 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.



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### 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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