

# SAFETY DATA SHEET

Version 6.5  
Revision Date 08/05/2024  
Print Date 08/06/2024

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

### 1.1 Product identifiers

Product name : Quetiapine hemifumarate salt

Product Number : Q3638  
Brand : Sigma  
CAS-No. : 111974-72-2

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

Identified uses : Laboratory chemicals, Synthesis of substances

Uses advised against : The product is being supplied under the TSCA R&D Exemption (40 CFR Section 720.36). It is the recipient's responsibility to comply with the requirements of the R&D exemption. The product may not be used for a non-exempt commercial purpose under TSCA unless appropriate consent is granted in writing by MilliporeSigma.

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

Company : Sigma-Aldrich Inc.  
3050 SPRUCE ST  
ST. LOUIS MO 63103  
UNITED STATES

Telephone : +1 314 771-5765  
Fax : +1 800 325-5052

### 1.4 Emergency telephone

Emergency Phone # : 800-424-9300 CHEMTREC (USA) +1-703-527-3887 CHEMTREC (International) 24 Hours/day; 7 Days/week

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 4), H302  
Short-term (acute) aquatic hazard (Category 1), H400  
Long-term (chronic) aquatic hazard (Category 1), H410

For the full text of the H-Statements mentioned in this Section, see Section 16.

Sigma - Q3638

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## 2.2 GHS Label elements, including precautionary statements

Pictogram



Signal Word

Warning

Hazard Statements

H302

Harmful if swallowed.

H410

Very toxic to aquatic life with long lasting effects.

Precautionary Statements

P264

Wash skin thoroughly after handling.

P270

Do not eat, drink or smoke when using this product.

P273

Avoid release to the environment.

P301 + P312 + P330

IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

P391

Collect spillage.

P501

Dispose of contents/ container to an approved waste disposal plant.

## 2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

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### SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Synonyms : 2-[2-(4-Dibenzo[b,f][1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]ethanol hemifumarate  
Quetiapine fumarate

Formula :  $C_{21}H_{25}N_3O_2S \cdot 0.5C_4H_4O_4$

Molecular weight : 441.54 g/mol

CAS-No. : 111974-72-2

| Component                      | Classification   | Concentration |
|--------------------------------|--|---------------|
| <b>QUETIAPINE HEMIFUMARATE</b> |  |               |
|                                | Acute Tox. 4; Aquatic Acute 1; Aquatic Chronic 1; H302, H400, H410<br>M-Factor - Aquatic Acute: 10 | <= 100 %      |

For the full text of the H-Statements mentioned in this Section, see Section 16.

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### SECTION 4: First aid measures

#### 4.1 Description of first-aid measures

No data available

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

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

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

No data available

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### **SECTION 5: Firefighting measures**

#### **5.1 Extinguishing media**

No data available

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

Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Sulfur oxides

#### **5.3 Advice for firefighters**

No data available

#### **5.4 Further information**

No data available

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### **SECTION 6: Accidental release measures**

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

For personal protection see section 8.

#### **6.2 Environmental precautions**

No data available

#### **6.3 Methods and materials for containment and cleaning up**

No data available

#### **6.4 Reference to other sections**

For disposal see section 13.

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### **SECTION 7: Handling and storage**

#### **7.1 Precautions for safe handling**

For precautions see section 2.2.

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

**Storage stability** Recommended storage temperature

2 - 8 °C

Store with desiccant.

##### **Storage class**

Storage class (TRGS 510): 11: Combustible Solids

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

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

No data available

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- |   |                      |
|---|----------------------|
| a) Appearance                                   | Form: solid          |
| b) Odor   | No data available    |
| c) Odor Threshold                               | No data available    |
| d) pH   | No data available    |
| e) Melting point/freezing point                 | No data available    |
| f) Initial boiling point and boiling range      | No data available    |
| g) Flash point                                  | ( )No data available |
| h) Evaporation rate                             | No data available    |
| i) Flammability (solid, gas)                    | No data available    |
| j) Upper/lower flammability or explosive limits | No data available    |
| k) Vapor pressure                               | No data available    |
| l) Vapor density                                | No data available    |
| m) Density                                      | No data available    |
| Relative density                                | No data available    |
| n) Water solubility                             | No data available    |
| o) Partition coefficient: n-octanol/water       | log Pow: 2.208       |
| p) Autoignition temperature                     | No data available    |
| q) Decomposition temperature                    | No data available    |

- r) Viscosity No data available
- s) Explosive properties No data available
- t) Oxidizing properties No data available

## 9.2 Other safety information

No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

No data available

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

No data available

### 10.5 Incompatible materials

Strong oxidizing agents

### 10.6 Hazardous decomposition products

In the event of fire: see section 5

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

LDLO Oral - Human - 70 mg/kg

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste):Eye:Mydriasis (pupillary dilation).

Behavioral:Toxic psychosis.

Behavioral:Convulsions or effect on seizure threshold.

Inhalation: No data available

Dermal: No data available

No data available

#### Skin corrosion/irritation

Remarks: No data available

#### Serious eye damage/eye irritation

Remarks: No data available

#### Respiratory or skin sensitization

No data available

#### Germ cell mutagenicity

No data available

## **Carcinogenicity**

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

## **Reproductive toxicity**

No data available

No data available

## **Specific target organ toxicity - single exposure**

No data available

## **Specific target organ toxicity - repeated exposure**

No data available

## **Aspiration hazard**

No data available

## **11.2 Additional Information**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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## **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

### **12.5 Results of PBT and vPvB assessment**

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

### **12.6 Endocrine disrupting properties**

No data available

### **12.7 Other adverse effects**

No data available

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

No data available

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**SECTION 14: Transport information****DOT (US)**

Not dangerous goods

**IMDG**

UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F

Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (QUETIAPINE HEMIFUMARATE)

Marine pollutant : yes

Marine pollutant : no

**IATA**

UN number: 3077 Class: 9 Packing group: III

Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (QUETIAPINE HEMIFUMARATE)

**Further information**

EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids. Packages smaller than or equal to 5 kg / L , not dangerous goods of Class 9

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**SECTION 15: Regulatory information****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

| Components | CAS-No. | Component TPQ (lbs) |
|------------|---------|---------------------|
|------------|---------|---------------------|

**SARA 311/312 Hazards** : Acute Health Hazard

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

## **US State Regulations**

### **Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

### **Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

### **Pennsylvania Right To Know**

QUETIAPINE HEMIFUMARATE 111974-72-2

### **Maine Chemicals of High Concern**

Product does not contain any listed chemicals

### **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

### **Washington Chemicals of High Concern**

Product does not contain any listed chemicals

### **New Jersey Right To Know**

QUETIAPINE HEMIFUMARATE 111974-72-2

### **The ingredients of this product are reported in the following inventories:**

TSCA : Product contains substance(s) not listed on TSCA inventory.

### **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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## **SECTION 16: Other information**

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact [mlsbranding@sial.com](mailto:mlsbranding@sial.com).

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