

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

<b>Catalogue Number</b>	CS-O-63539
<b>Product Name</b>	Maralixibat
<b>CAS No.</b>	716313-53-0
<b>Category</b>	API
<b>Synonyms</b>	1-(4-((4-((4R,5R)-3,3-dibutyl-7-(dimethylamino)-4-hydroxy-1,1-dioxido-2,3,4,5-tetrahydrobenzo[b]thiepin-5-yl)phenoxy)methyl)benzyl)-1,4-diazabicyclo[2.2.2]octan-1-ium
<b>Brand</b>	Clearsynth Labs Ltd.
<b>Identified uses</b>	Laboratory Chemicals
<b>Uses advised against</b>	Not available
<b>Company</b>	Clearsynth Labs Ltd. Mumbai, India
<b>Emergency Phone #</b>	+91-22-245045900
<b>REACH No.</b>	Not available

### SECTION 2: Hazards identification

**Disclaimer:** This is sample MSDS. Please email [sales@clearsynth.com](mailto:sales@clearsynth.com) for more details.

#### 2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Not available

#### 2.2 Label Elements

**Signal Word:** Not available

Not available

#### Hazard Statement(s)

Code	Statement
Not available	Not available

#### Precautionary Statement(s)

Code	Statement
Not available	Not available

### SECTION 3: Composition / information on ingredients

### 3.1 Substance

Component : Maralixibat

CAS Number : 716313-53-0

Molecular Formula : C<sub>40</sub>H<sub>56</sub>N<sub>3</sub>O<sub>4</sub>S+

Molecular Weight : 674.96

Parent Chemical : Maralixibat

Synonyms : 1-(4-((4-((4R,5R)-3,3-dibutyl-7-(dimethylamino)-4-hydroxy-1,1-dioxido-2,3,4,5-tetrahydrobenzo[b]thiepin-5-yl)phenoxy)methyl)benzyl)-1,4-diazabicyclo[2.2.2]octan-1-ium

Concentration : Not available

## SECTION 4: First aid measures

### SECTION 4: First-aid measures

#### 4.1 Description of first aid measures

- General advice: Seek medical attention if symptoms occur or persist. Show this SDS to medical personnel.
- Inhalation: Move person to fresh air. If breathing is difficult, seek medical attention.
- Skin contact: Wash with plenty of soap and water. Remove contaminated clothing and wash before reuse. Get medical attention if irritation develops.
- Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention if irritation persists.
- Ingestion: Rinse mouth. Do not induce vomiting unless directed by medical personnel. Seek medical attention.

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

- Not available.

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

- Treat symptomatically. No data available.

## SECTION 5: Firefighting measures

### SECTION 5: Fire-fighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media: Water spray, alcohol-resistant foam, dry chemical, carbon dioxide.
- Unsuitable extinguishing media: Not available.

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

- Specific hazards: Not available.
- Hazardous combustion products: Not available.

#### 5.3 Advice for firefighters

- Wear self-contained breathing apparatus (SCBA) and full protective gear.
- Use water spray to cool unopened containers.
- Avoid inhalation of combustion products.

## SECTION 6: Accidental release measures

### SECTION 6: Accidental release measures

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

- Avoid breathing dust/mist/vapors.
- Use appropriate personal protective equipment (see Section 8).
- Ensure adequate ventilation.

### 6.2 Environmental precautions

- Prevent further leakage or spillage if safe to do so.
- Avoid release to the environment. No data available on environmental hazards.

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

- Contain spill.
- Collect spilled material using methods that minimize dust generation.
- Place in a suitable, closed container for disposal.
- Clean contaminated area with appropriate cleaning methods. Do not flush to drain.

### 6.4 Reference to other sections

- See Section 8 for personal protective equipment and Section 13 for disposal considerations.

## SECTION-7: Handling and storage

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

- Handle in accordance with good industrial hygiene and safety practice.
- Avoid contact with skin and eyes.
- Avoid breathing dust/aerosols.
- Use with adequate ventilation.
- Keep container tightly closed when not in use.

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

- Store in a cool, dry, well-ventilated place.
- Keep in original container, tightly closed.
- Protect from moisture. Protect from incompatible materials.
- Incompatible materials: Not available.

#### 7.3 Specific end use(s)

- API / laboratory or research use. Not available for other specific uses.

## SECTION 8: Exposure controls / personal protection

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

- Occupational exposure limits: No data available.
- Biological limit values: Not available.

#### 8.2 Exposure controls

- Engineering controls: Use local exhaust ventilation or other engineering controls to maintain airborne levels as low as practicable.
- Personal protective equipment (PPE):
- Eye/face protection: Safety glasses with side shields or chemical goggles.

- Skin protection: Protective gloves (material not specified). Protective clothing as appropriate.
- Respiratory protection: If ventilation is inadequate or dust/aerosols are generated, use an appropriate respirator.
- Hygiene measures: Wash hands after handling. Remove contaminated clothing and wash before reuse.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available
c) Odor	No data available
d) pH	No data available
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available
p) Solubility (in DMSO)	No data available

Property	Value
q) Oxidizing Properties	No data available

### SECTION 10: Stability and reactivity

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##### 10.1 Reactivity

- Not available.

##### 10.2 Chemical stability

- Stable under recommended storage conditions. No data available.

##### 10.3 Possibility of hazardous reactions

- Not available.

##### 10.4 Conditions to avoid

- Avoid dust generation and exposure to moisture/heat as a general precaution. Specific conditions: Not available.

##### 10.5 Incompatible materials

- Not available.

##### 10.6 Hazardous decomposition products

- Not available.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

- Acute toxicity: No data available.
- Skin corrosion/irritation: No data available.
- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: No data available.
- Carcinogenicity: No data available.
- Reproductive toxicity: No data available.
- STOT-single exposure: No data available.
- STOT-repeated exposure: No data available.
- Aspiration hazard: No data available.

#### Likely routes of exposure

- No data available.

#### Symptoms related to the physical, chemical and toxicological characteristics

- In trials of maralixibat in children with Alagille syndrome, serum ALT levels rose to greater than 3 times ULN in 24% of patients and above 5 times ULN in 2%. The ALT elevations led to dose modification, interruption or therapy or early discontinuation in up to 10% of patients. Children with Alagille syndrome and other pediatric cholestatic liver diseases typically have serum aminotransferase elevations in the range of 2 to 5 times ULN, and it is can be difficult to distinguish between spontaneous fluctuations in enzyme levels due to the underlying disease vs effects of maralixibat therapy. In most instances, therapy can be continued despite the serum enzyme elevations, at least at a reduced dosage. There have been no reports of clinically apparent liver injury with jaundice attributed to maralixibat therapy, but it has had limited general clinical use. Likelihood score: E\* (suspected but unproven cause of clinically

apparent liver injury).

## SECTION 12: Ecological information

### SECTION 12: Ecological information

#### 12.1 Toxicity

- Not available.

#### 12.2 Persistence and degradability

- Not available.

#### 12.3 Bioaccumulative potential

- Not available.

#### 12.4 Mobility in soil

- Not available.

#### 12.5 Results of PBT and vPvB assessment

- Not available.

#### 12.6 Endocrine disrupting properties

- Not available.

#### 12.7 Other adverse effects

- Not available.

## SECTION 13: Disposal considerations

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

- Dispose of contents/container in accordance with local/regional/national/international regulations.
- Do not discharge to drains or the environment.
- Recommended disposal method: Not available (dependent on form and contamination).
- Contaminated packaging: Dispose of as unused product unless cleaned and permitted by regulations.

## SECTION 14: Transport information

### SECTION 14: Transport information

- UN number: Not available.
- UN proper shipping name: Not available.
- Transport hazard class(es): Not available.
- Packing group: Not available.
- Environmental hazards: Not available.
- Special precautions for user: Not available.
- Transport in bulk according to IMO instruments: Not available.

## SECTION 15: Regulatory information

### SECTION 15: Regulatory information

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

- Regulatory status (inventory listings, classifications): Not available.

#### 15.2 Chemical safety assessment

- Not available.

### SECTION 16: Other information

#### SECTION 16: Other information

- Product name: Maralixibat
- CAS No.: 716313-53-0
- Catalog No.: CS-O-63539
- Category: API
- Supplier: Clearsynth Labs Ltd., Mumbai, India
- Emergency phone: +91-22-245045900

#### Disclaimer

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