

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

Catalogue Number	CS-AV-00024
Product Name	Siponimod
CAS No.	1230487-00-9
Category	API
Synonyms	1-({4-[(1E)-1-({[4-Cyclohexyl- 3-(trifluoromethyl)phenyl]methoxy}imino)ethyl]-2-ethylphenyl)methyl)azetidine-3-carboxylic Acid
Brand	Clearsynth Labs Ltd.
Identified uses	Laboratory Chemicals
Uses advised against	Not available
Company	Clearsynth Labs Ltd. Mumbai, India
Emergency Phone #	+91-22-245045900
REACH No.	Not available

SECTION 2: Hazards identification

Disclaimer: This is sample MSDS. Please email 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 : Siponimod

CAS Number : 1230487-00-9

Molecular Formula : C₂₉H₃₅F₃N₂O₃

Molecular Weight : 516.6

Parent Chemical : Siponimod

Synonyms : 1-({4-[(1E)-1-({[4-Cyclohexyl-

3-(trifluoromethyl)phenyl]methoxy)imino)ethyl]-2-ethylphenyl)methyl)azetidine-3-carboxylic Acid

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 Safety Data Sheet 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.
- Seek 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, or carbon dioxide.

Unsuitable extinguishing media:

- Not available.

5.2 Special hazards arising from the substance or mixture

- Combustible solid (classification not available).
- Thermal decomposition may produce irritating and/or toxic fumes.
- 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.
- Avoid contact with skin and eyes.
- Use appropriate personal protective equipment (see Section 8).
- Ensure adequate ventilation.

6.2 Environmental precautions

- Avoid release to the environment.
- Prevent entry into drains, sewers, or waterways.

6.3 Methods and material for containment and cleaning up

- Avoid generating dust.
- Collect spilled material using suitable means (e.g., HEPA-filter vacuum or damp method) and place in a suitable, labeled container for disposal.
- Clean contaminated area with appropriate cleaning method; do not dry sweep.

6.4 Reference to other sections

- See Section 8 for exposure controls/personal protection.
- See 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 formation of dust and aerosols.
- Avoid contact with skin, eyes, and clothing.
- Use with adequate ventilation; use local exhaust where dust may be generated.
- Wash hands thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

- Store in a tightly closed container.

- Keep in a cool, dry, well-ventilated place.
- Protect from moisture.
- Incompatible materials: Not available.

7.3 Specific end use(s)

- API / laboratory or industrial use. Specific uses: Not available.

SECTION 8: Exposure controls / personal protection

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits:

- Not available.

Biological limit values:

- Not available.

8.2 Exposure controls

Engineering controls:

- Provide adequate general ventilation.
- Use local exhaust ventilation where dust may be generated.

Personal protective equipment (PPE):

Eye/face protection:

- Safety glasses with side shields or chemical splash goggles.

Skin protection:

- Protective gloves (material not specified).
- Protective clothing as appropriate.

Respiratory protection:

- If dust or aerosols are generated, use a suitable particulate respirator per applicable standards.

Hygiene measures:

- Do not eat, drink, or smoke when using this product.
- Wash hands and exposed skin after handling.

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
q) Oxidizing Properties	No data available

SECTION 10: Stability and reactivity

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10.1 Reactivity

- No data available.

10.2 Chemical stability

- Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

- No data available.

10.4 Conditions to avoid

- Avoid dust formation.

- Avoid heat and sources of ignition.

- Avoid moisture (if applicable): 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: In large controlled trials of siponimod in patients with multiple sclerosis, serum ALT elevations were common, typically arising during the first 3 months of treatment. The elevations were generally mild and asymptomatic, and they often returned to baseline values even with continuation of treatment or within 3 months of stopping. Aminotransferase elevations above 3 times upper limit of normal (ULN) were reported in 6% to 8% of siponimod recipients compared to less than 2% of placebo recipients. In these prelicensure clinical trials, there were no cases of acute hepatitis or clinically apparent liver injury but elevations in liver tests led to discontinuation in 1% of subjects. While siponimod is associated with lymphopenia and long term therapy is associated with risk for reactivation of herpes simplex and zoster infections, it has not been linked to cases of reactivation of hepatitis B, although one such instance has been reported with fingolimod. Thus, mild-to-moderate and transient serum enzyme elevations during therapy are not uncommon, but clinically apparent liver injury with jaundice due to siponimod must be rare if it occurs at all. Likelihood score: E* (suspected but unproven cause of clinically apparent liver injury).

- 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 large controlled trials of siponimod in patients with multiple sclerosis, serum ALT elevations were common, typically arising during the first 3 months of treatment. The elevations were generally mild and asymptomatic, and they often returned to baseline values even with continuation of treatment or within 3 months of stopping. Aminotransferase elevations above 3 times upper limit of normal (ULN) were reported in 6% to 8% of siponimod recipients compared to less than 2% of placebo recipients. In these prelicensure clinical trials, there were no cases of acute hepatitis or clinically apparent liver injury but elevations in liver tests led to discontinuation in 1% of subjects. While siponimod is associated with lymphopenia and long term therapy is associated with risk for reactivation of herpes simplex and zoster infections, it has not been linked to cases of reactivation of hepatitis B, although one such instance has been reported with fingolimod. Thus, mild-to-moderate and transient serum enzyme elevations during therapy are not uncommon, but clinically apparent liver injury with jaundice due to siponimod must be rare if it occurs at all. Likelihood score: E* (suspected but unproven cause of clinically apparent liver injury).

SECTION 12: Ecological information

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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

- Not available.

12.6 Endocrine disrupting properties

- Not available.

12.7 Other adverse effects

- No data available.

SECTION 13: Disposal considerations

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13.1 Waste treatment methods

Product:

- Dispose of contents/container in accordance with local/regional/national/international regulations.
- Do not discharge to drains.

Contaminated packaging:

- Dispose of as unused product in accordance with applicable regulations.

Waste code:

- Not available.

SECTION 14: Transport information

SECTION 14: Transport information

14.1 UN number

- Not available.

14.2 UN proper shipping name

- Not available.

14.3 Transport hazard class(es)

- Not available.

14.4 Packing group

- Not available.

14.5 Environmental hazards

- Not available.

14.6 Special precautions for user

- Not available.

14.7 Transport in bulk according to IMO instruments

- Not available.

SECTION 15: Regulatory information

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

- Regulatory status: Not available.

- GHS classification: Not available.

- Hazard statements/precautionary statements: Not available.

15.2 Chemical safety assessment

- No data available.

SECTION 16: Other information

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Product identifier:

- Product name: Siponimod

- CAS No.: 1230487-00-9

- Catalog No.: CS-AV-00024

- Category: API

- Molecular weight: 516.6

- Synonyms: 1-({4-[(1E)-1-({4-Cyclohexyl-3-(trifluoromethyl)phenyl}methoxy)imino)ethyl]-2-ethylphenyl)methyl)azetidine-3-carboxylic Acid

Supplier:

- Clearsynth Labs Ltd., Mumbai, India

Emergency telephone:

- +91-22-245045900

Disclaimer:

- The information provided in this SDS is based on data believed to be accurate; however, no warranty is expressed or implied regarding the accuracy or completeness of this information.

- Users are responsible for determining the suitability of this information for their particular use and for compliance with applicable laws and regulations.

Revision information:

- Revision date: Not available.

- Version: Not available.

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