



MSN Laboratories Private Limited
R&D Center, Formulation Division.

SAFETY DATA SHEET

Product Name	Sacubitril and Valsartan Tablets 24/26 mg, 49/51 mg and 97/103 mg	Page No 1 of 3
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1. Identification

Product Name: Sacubitril and Valsartan Tablets 24/26 mg, 49/51 mg and 97/103 mg

Chemical Family: Mixture

Intended use: To treat chronic heart failure in adults.

Details of the manufacturer:

Msn laboratories private limited.

Formulation division, Unit-II

Sy.No. :1277, 1319 to 1324, Nandigama (Village & Mandal),

Rangareddy (District),Telangana-509228, India

2. Hazards Identification

Hazard Statements: Harmful if swallowed

Prevention: Wash face, hands and any exposed skin thoroughly after handling.

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

Disposal: Dispose of contents/container to an approved waste disposal plant

3. Composition/Information on Ingredients

C.A.S. No : 936623-90-4

Molecular Formula : $C_{48}H_{55}N_6O_8Na_3$

Formula Weight : 912.96

Chemical Name : Tri sodium (4- {[(1 S,3R)-1-([1,1'-biphenyl] 4-yl)methyl)-4-ethoxy-3-methyl-4-oxobutyl]amino}-4-oxobutanoate)-(N-pentanoyl-N- {[2'-(1H-tetrazol-1-yl)-5-yl][1,1'-biphenyl]-4-yl]methyl}-L-valinate

4. First Aid Measures

General Advice: If symptoms persist, call a physician.

Eye Contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

Skin Contact: Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

Ingestion: Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

Most important symptoms and effects: None reasonably foreseeable

5. Fire Fighting Measures

Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical, CO₂, water spray or alcohol-resistant foam.

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6. Accidental Release Measures

Personal Precautions: Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

Environmental Precautions: Should not be released into the environment

Methods for Containment and Clean-up: Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal

7. Handling and Storage

Handling: Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

Storage Conditions: Store below 25°C

8. Exposure Controls/Personal Protection

Exposure Guidelines: This product does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.

Engineering Measures: Ensure adequate ventilation, especially in confined areas.

Personal Protective Equipment:

Eye/face Protection: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin and body protection: Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection: Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirators if exposure limits are exceeded or if irritation or other symptoms are experienced.

9. Physical and Chemical Properties

Physical state: Tablet / film coated tablets

Description:

24/26mg: Purple colored, Oval shaped biconvex, film coated tablets one side debossed with "M" and other side debossed with "S1"

49/51mg: Light yellow to yellow colored, Oval shaped, biconvex, film coated tablets one side debossed with "M" and other side debossed with "S2"

97/103mg: Light pink to pink colored, oval shaped, biconvex, film coated tablets one side debossed with "M" and other side debossed with "S3"

10. Stability and Reactivity

Reactive Hazard: None known, based on information available

Conditions to Avoid: Incompatible products

Incompatible products: Oxidizing agent

Hazardous Decomposition Products: Carbon monoxide (CO), Carbon dioxide (CO₂), Hydrogen fluoride, Nitrogen oxides (NO_x)

Hazardous Polymerization: Hazardous polymerization does not occur.

Hazardous Reactions: None under normal processing.

10. Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

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11. Toxicological Information

Carcinogenicity: Oral LD50 >2 g/kg (rat)

Ecotoxicity: Do not empty into drains.

12. Ecological Information

Ecotoxicity

Ecotoxicity effects: This product has no known eco-toxicological effects.

Aquatic toxicity effects: This product has no known aquatic toxicological effects.

13. Disposal Considerations

Waste Disposal Methods: - Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport Information

Not Regulated any information related to transport.

15. Regulatory Information

California Proposition 65: This product does not contain any Proposition 65 chemicals.

Security: This product does not contain any DHS chemicals.

16. Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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