

MATERIAL SAFETY DATA SHEET



1. PRODUCT AND COMPANY IDENTIFICATION

Name: Sacubitril and Valsartan Film-Coated Tablets 24/26mg, 49/51mg, 97/103mg

Pharmacological action: antihypertensive agent

Usage: Drug product (pharmaceutical bulk, primary packed, finished product)

Company name: AET Laboratories Private Limited
Survey No. 42, Gaddapotharam,
Kazipally Industrial Area, Sangareddy Dist., Hyderabad,
Telangana, INDIA, 502319
Tel: 040-31902936/37/38

2. HAZARD(S) IDENTIFICATION

GHS Hazard Phrases: H317: May cause an allergic skin reaction. H319: Causes serious eye irritation.

GHS Precaution Phrases: P264 – Wash {hands} thoroughly after handling.

P280 – Wear Protective gloves/protective clothing/eye protection/face protection.

GHS Response Phrases: P302: If on skin wash with plenty of soap and water.

3. COMPOSITION / INFORMATION ON INGREDIENTS:

For classification of declared components, see section 15, “Regulatory information”

Chemical Name	%w/w	CAS Number
Sacubitril sodium	24.6	149709-62-6
Valsartan disodium	27.2	137862-53-4
Silicon dioxide	5.1	-
Microcrystalline cellulose	9.2	-
Low substituted hydroxy propyl cellulose	7.2	-
Crospovidone	7.2	-
Mannitol	10.8	-
Magnesium stearate	2.9	-
Talc	~ 1	-
Hypromellose	~ 2	-
Titanium dioxide	~ 1	-
Macrogol	~ 0.5	-

The remaining components are inert ingredients.

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For TLV values of declared components, see Section 8 , Exposure controls / personal

4 FIRST AID MEASURES

In case of contact with the eyes rinse thoroughly with plenty of running water for at least 15 minutes and consult a physician. In case of contact of the skin, remove contaminated clothing and wash the contaminated skin immediately with soap and plenty of water and seek medical advice. In case of Inhalation, remove the victim from danger zone, avoid further exposure. If swallowed, seek medical advice immediately and show this container or label.

5 FIRE FIGHTING MEASURES

Extinguishing media water spray. Carbon dioxide, dry chemical powder or appropriate foam. Special firefighting procedures, wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Unusual fire and explosions hazards. Emits toxic fumes under fire conditions.

6 ACCIDENTAL RELEASE MEASURES

Wear respirator, chemical safety goggles, rubber boots and heavy Rubber gloves. Sweep up, place it in a bag and hold it for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

7 HANDLING AND STORAGE

7.1 Handling: No special handling requirements for normal use of this material.

7.2 Storage: Store in a dry and cool place, at controlled room temperature 59°F to 86°F (15°C to 30°C).

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8 EXPOSURE CONTROLS / PERSONAL PROTECTION:

List type	Component	Value unit
Occupational Exposure Limit (OEL):	Sacubitril:	0.25 mg/m ³ /day
	Valsartan:	0.005 mg/m ³ /day

Remaining components are inert ingredients

Personal protection for open handling:

- Chemical safety goggles
- Compatible chemical-resistant gloves
- Niosh/msha-approved respirator
- Safety shower and eye bath
- Mechanical exhaust required
- Avoid inhalation
- Avoid contact with eyes, skin and clothing
- Avoid prolonged or repeated exposure
- Keep tightly closed
- Store in a cool dry place

9 PHYSICAL AND CHEMICAL PROPERTIES

Formulation : Tablet

Flash point : not applicable

10 PRODUCT STABILITY AND REACTIVITY

Under the normal conditions of use, the product is stable.

11 TOXICOLOGICAL INFORMATION

- Acute effects May be harmful by ingestion.
- May cause eye irritation.
- To the best of our knowledge, the chemical, physical, and Toxicological properties have not been thoroughly investigated.

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12 ECOLOGICAL INFORMATION:

- Avoid release in to the environment.
- Runoff from fire control or dilution water may cause pollution.

13 DISPOSAL CONSIDERATIONS

- It should be taken care that rejected products/returned goods are not resold or reused.
- Local and National regulations are to be observed before disposing of this product.

14 TRANSPORT INFORMATION

“Transport in accordance with local, state, and federal regulations.”

Regulation	Class	Un No.	PG	Label	LQ
RID/ADR	Not restricted	0			
IMDG code	Not restricted	0			
ICAO/IATA-DGR	Not restricted	0			

- No Dangerous Goods.

15 REGULATORY INFORMATION

WHMIS Classification : Not applicable
OSHA : Not applicable
SERA : Not applicable
TSCA : Not applicable

16 OTHER INFORMATION

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.