



Section 1: Identification	
Product Name	Sacubitril and Valsartan Tablets 24mg/26mg, 49mg/51mg and 97mg/103mg
Recommended use	Pharmaceutical product
Manufacturer	Hetero Labs Limited, Unit-III 22-110, IDA, Unit III, Jeedimetla, Hyderabad-500055, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)	Acute toxicity, oral Skin corrosion/irritation Serious eye damage/eye irritation Specific target organ toxicity, single exposure; Respiratory tract irritation
GHS Label elements, including precautionary statements	Hazard statement(s) <u>Prevention</u> Avoid breathing dust/fume/gas/mist/vapours/spray Wash hands thoroughly after handling Do not eat, drink or smoke when using this product Use only outdoors or in a well-ventilated area
IF ON SKIN IF INHALED IF IN EYES	Wash with plenty of soap and water Remove victim to fresh air and keep at rest in a position comfortable for breathing Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing Rinse mouth Take off contaminated clothing and wash it before reuse.
Storage	Store in a well-ventilated place. Keep container tightly closed.
Disposal	Dispose of contents/container to in accordance with local regulation
Other hazards	None



Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Sacubitril/Valsartan	936623-90-4
Crospovidone	9003-39-8
Isopropyl Alcohol	67-63-0
Low-Substituted Hydroxypropyl Cellulose	9004-64-2
Magnesium Stearate	557-04-0
Methylene chloride	75-09-2
Microcrystalline Cellulose	9004-34-6
Opadry Blue	117698-04-1
Opadry Brown	117698-04-1
Opadry white	117698-04-1
Povidone,	9003-39-8
Silicon Dioxide	14808-60-7
Section 4: First-Aid Measures	
Eye contact	Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.
Skin contact	Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.
Inhalation	Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation
Ingestion	Wash out mouth with water; Do NOT induce vomiting; call a physician
Indication of any immediate medical attention and special treatment needed	Treat symptomatically
Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher.
Special hazards arising from the substance or mixture	During combustion, may emit irritant fumes.
Advice for firefighters	Wear self-contained breathing apparatus and protective clothing.



Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Use full personal protective equipment. Avoid breathing vapors, mist, dust or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.
Environmental precautions	Try to prevent further leakage or spillage. Keep the product away from drains or water courses
Methods and materials for containment and cleaning up	Absorb solutions with finely-powdered liquid-binding material (diatomite, universal binders); Decontaminate surfaces and equipment by scrubbing with alcohol;
Section 7: Handling and Storage	
Precautions for safe handling	Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation
Storage	Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].
Specific end use(s)	No data available
Section 8: Exposure Controls/Personal Protection	
Control parameters	Components with workplace control parameters This product contains no substances with occupational exposure limit values
Engineering controls	Ensure adequate ventilation. Provide accessible safety shower and eye wash station
Personal protective equipment Eye protection Hand protection Skin and body protection Respiratory protection Environmental exposure controls	Safety goggles with side-shields Protective gloves Impervious clothing Suitable respirator Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.
9: Physical and Chemical Properties	
Physical Form	Tablet
Description	<p>Sacubitril and Valsartan Tablets 24 mg/26 mg are white colored, oval shaped, film-coated tablets debossed with 'H' on one side and 'S24' on the other side.</p> <p>Bottle of 60 NDC 31722-673-60 Bottle of 180 NDC 31722-673-18</p> <p>Sacubitril and Valsartan Tablets 49 mg/51 mg are blue colored, oval shaped, film-coated tablets debossed with 'H' on one side and 'S25' on the other side.</p> <p>Bottle of 60 NDC 31722-674-60 Bottle of 180 NDC 31722-674-18</p>



	Sacubitril and Valsartan Tablets 97 mg/103 mg are brown colored, oval shaped, film-coated tablets debossed with 'H' on one side and 'S26' on the other side. Bottle of 60 NDC 31722-675-60 Bottle of 180 NDC 31722-675-18
Section 10: Stability and Reactivity	
Reactivity	No data available
Chemical stability	Stable under recommended storage conditions
Possibility of hazardous reactions	No data available.
Conditions to avoid	No data available
Incompatible materials	Strong acids/alkalis, strong oxidising/reducing agents
Hazardous decomposition products	Under fire conditions, may decompose and emit toxic fumes. Other decomposition products - no data available.
Section 11: Toxicological Information	
Carcinogenesis, Mutagenesis, Impairment of Fertility	<p>There was no evidence of carcinogenicity when valsartan was administered in the diet to mice and rats for up to 2 years at doses up to 160 and 200 mg/kg/day, respectively. These doses in mice and rats are about 2.6 and 6 times, respectively, the maximum recommended human dose on a mg/m² basis. (Calculations assume an oral dose of 320 mg/day and a 60 kg patient.) Mutagenicity assays did not reveal any valsartan-related effects at either the gene or chromosome level. These assays included bacterial mutagenicity tests with Salmonella (Ames) and E coli; a gene mutation test with Chinese hamster V79 cells; a cytogenetic test with Chinese hamster ovary cells; and a rat micronucleus test. Valsartan had no adverse effects on the reproductive performance of male or female rats at oral doses up to 200 mg/kg/day. This dose is 6 times the maximum recommended human dose on a mg/m² basis. (Calculations assume an oral dose of 320 mg/day and a 60-kg patient.)</p> <p>Valsartan – Oral LD₅₀ > 2000 mg/kg (Rat)</p>
Section 12: Ecological Information	
Toxicity	No data available
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Mobility in soil	No data available
Results of PBT and vPvB assessment	PBT/vPvB assessment unavailable as chemical safety assessment not required or not conducted
Other adverse effects	No data available



Section 13: Disposal Considerations	
Waste treatment methods	Dispose substance in accordance with prevailing country, federal, state and local regulations
Product	
Contaminated packaging	Conduct recycling or disposal in accordance with prevailing country, federal, state and local regulations
Section 14: Transport Information	
DOT (US)	Not dangerous goods
Proper shipping name:	
UN number:	
Class: -	
Packing group: -	
IMDG	Not dangerous goods
Proper shipping name:	
UN number	
Class: -	
Packing group: -	
IATA	Not dangerous goods
Proper shipping name:	
UN number: -	
Class: -	
Packing group: -	
Section 15: Regulatory Information	
SARA 302 Components	No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components	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.
SARA 311/312 Hazards	No SARA Hazards
Massachusetts Right To Know Components	No components are subject to the Massachusetts Right to Know Act.
Pennsylvania Right To Know Components	No components are subject to the Pennsylvania Right to Know Act.
New Jersey Right To Know Components	No components are subject to the New Jersey Right to Know Act



California Prop. 65 Components	This product does not contain any chemicals known to State of California to cause cancer, birth defects, or anyother reproductive harm.
Section 16: Other Information	
Issue Date : 03-06-2025	
Version : 00	
Further information	
Revision date: NA	
Revision note: NA	
<p>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.</p>	
<p>Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.</p>	