

SAFETY DATA SHEET

Section 1: Identification	
Material	Dabigatran capsules 75mg & 150mg
Recommended use	For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients
Manufacturer	Hetero Labs Limited Unit III
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
WARNING	This is a pharmaceutical product, designed to be prescribed by a licensed health care professional. Should any employee, while handling or processing this pharmaceutical preparation, observe any adverse health effects, they should contact their health care provider immediately. In addition, they should evacuate the work environment. Follow all instructions and packaging labels.
Classification according to Regulation (EC) No. 1272/2008:	This product is a non-hazardous mixture of single components and need not be labelled according to EC-Directive 1999/45/EC, as amended.
Section 3: Composition/Information on Ingredients	
Ingredients	Dabigatran etexilate
CAS	211915-06-9
Section 4: First-Aid Measures	
Inhalation	Keep patient calm, remove to fresh air, and seek medical attention.
Skin Contact	Wash off thoroughly with ample water. Seek medical attention.
Eye Contact	Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.
General advice	Remove from exposure, lie down. Immediately remove contaminated clothing. If danger of loss of consciousness, place patient in recovery position and transport accordingly. Apply artificial respiration if necessary. First aid personnel should pay attention to their own safety

Ingestion	Rinse mouth immediately and then drink plenty of water, seek medical attention.
Section 5: Fire-Fighting Measures	
Suitable Extinguishing Media	Use extinguishing measures to suit surroundings., Water, Dry chemical, Foam, carbon dioxide
Hazards during fire-fighting	In case of fire and/or explosion do not breathe fumes. Can be released in case of fire:, Carbon oxides, nitrogen oxides, Sulfur oxides
Protective equipment for fire-fighting	Wear self-contained breathing apparatus and chemical protective clothing.
Further information	Collect separately contaminated extinguishing water, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.
Section 6: Accidental Release Measures	
Methods for cleaning-up or taking-up	For large amounts: Dampen, pick up mechanically and dispose of. Avoid raising dust. For residues: Use approved industrial vacuum cleaner for removal. Pack in tightly closed containers for disposal.
Personal Precautions:	Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation.
Environmental Precautions:	Do not discharge into drains/surface waters/groundwater.
Additional information	Never return spills in original containers for re-use.
Section 7: Handling and Storage	
Handling: Precautions for safe handling: Hygienic measures	Do not open until use. Provide good ventilation of working area (local exhaust ventilation if necessary). Keep away from sources of ignition - No smoking. Protect from moisture. General safety and hygiene measures. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.
Storage:	Store in accordance with information listed on the product insert.
Section 8: Exposure Controls/Personal Protection	
Respiratory protection	Use breathing apparatus if exposed to vapors/dust/aerosol.
Hand protection	Chemical resistant protective gloves
Eye protection	Safety glasses with side-shields
Body protection	Laboratory: laboratory coat.

General protective measures	Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.
Section 9: Physical and Chemical Properties	
Physical Form	Solid
Colour	75 mg - cream opaque cap / cream opaque body filled with off white to yellowish white pellets 150 mg - cream opaque cap / cream opaque body filled with off white to yellowish white pellets
Description	Dabigatran etexilate 75 mg capsules are cream opaque cap / cream opaque body size '2' HPMC capsules imprinted with 'H' on cap and 'D10' on body with black ink, filled with mixture of off white to yellowish white pellets. The capsules are supplied in the packages listed: Unit of use bottle of 60 capsules NDC 31722-621-60 Dabigatran etexilate 150 mg capsules are light cream opaque cap / cream opaque body size '0' HPMC capsules imprinted with 'H' on cap and 'D11' on body with black ink, filled with mixture of off white to yellowish white pellets. The capsules are supplied in the packages listed: Unit of use bottle of 60 capsules NDC 31722-622-60
Section 10: Stability and Reactivity	
No further relevant information available.	
Section 11: Toxicological Information	
Acute oral toxicity	LD50 > 2000 mg/kg rat The values mentioned are those of the active ingredient.
Acute inhalation toxicity	No data available.
Acute dermal toxicity	No data available.
Skin irritation	Non-irritant (rabbit) The values mentioned are those of the active ingredient.
Eye irritation	No data available
Sensitization	Did not cause sensitization on laboratory animals. The values mentioned are those of the active ingredient.
Genetic toxicity in vitro	Ames-test Salmonella typhimurium Result: negative Method: OECD Guideline 471 The values mentioned are those of the active ingredient. Mouse lymphoma assay mouse lymphoma cells

	Result: negative Method: OECD Guideline 476 The values mentioned are those of the active ingredient
Genetic toxicity in vivo	Micronucleus assay rat Result: negative Method: OECD Guideline 474 The values mentioned are those of the active ingredient.
Carcinogenicity	Dose: 30, 100 ,200 mg/kg/day (rat) Did not show carcinogenic effects in animal experiments
Reproductive toxicity	Study for Effects on Embryo-Fetal Development rat NOAEL Parents: 200 mg/kg The values mentioned are those of the active ingredient Pre- and Postnatal development study rabbit NOAEL Parents: 30 mg/kg NOAEL F1-Generation: 70 mg/kg Did not show teratogenic effects in animal experiments, The values mentioned are those of the active ingredient
Aspiration hazard	No data available
Section 12: Ecological Information	
<p>Ecotoxicity Toxicity to fish : No data available. Toxicity to daphnia : EC50 > 100,0 mg/l (Daphnia magna) Exposition time: 48 h Method: OECD Test Guideline 202 The values mentioned are those of the active ingredient. Toxicity to algae : No data available Toxicity to bacteria : No data available. Chronic toxicity to fish : No data available. Chronic toxicity to aquatic invertebrates : No data available.</p> <p>Persistence and degradability Biological degradation : Not biologically degradable 14 % Exposition time: 28 d Method: OECD 301 B Guideline The values mentioned are those of the active ingredient. Transport between environmental compartments : No data available. Bioaccumulation : No data available. PBT and vPvB assessment : No data available.</p>	
Section 13: Disposal Considerations	
<p>Product : Dispose of in accordance with local regulations. Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.</p>	
Section 14: Transport Information	
UN-Number DOT,IMDG,IATA	Not Regulated
UN proper shipping name DOT,IMDG,IATA	Not Regulated
Transport hazard class(es) DOT,AND,IMDG,IATA	Not Regulated
Packing group DOT,IMDG,IATA	Not Regulated

Enviromental hazards	Not applicable
Special precautions for user	Not applicable
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code	Not applicable
UN “Model regulation”	Not Regulated
Section 15: Regulatory Information	
National legislation/regulations Water hazard class : VVWS WGK 1 slightly water endangering Annex 4 VwVwS (Germany) dated Mai, 17 th 1999	
Section 16: Other Information	
<p>Issue Date: 07-06-2022</p> <p>Version: 00</p> <p>Further information</p> <p>Revision date: New issue</p> <p>Revision note: New issue</p> <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>	