



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

SAFETY DATA SHEET

Product Name: Dabigatran Etexilate Capsules 75 mg, 110 mg and 150 mg

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1. Product Information

Product Name: Dabigatran Etexilate Capsules 75 mg, 110 mg and 150 mg

2. Composition

C.A.S. No : 872728-81-9
Molecular Formula : $C_{34}H_{45}N_7O_8S$
Molecular Weight : 723.86
Chemical Name : N-[[2-[[[4-[[[(hexyloxy)carbonyl]amino]iminomethyl] phenyl]amino]methyl]-1-methyl-1H-benzimidazol-5-yl]carbonyl]-N-2-pyridinyl-,ethyl ester, methanesulfonate.

3. Hazards Identification

Use appropriate procedures to prevent opportunities for direct contact with the skin or eyes and to prevent inhalation. Non-Flammable.

4. First Aid Measures

Eye Contact: Check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.

Skin Contact: Flush with copious amounts of water; remove contaminated clothing and shoes; call a physician.

Ingestion: If swallowed, wash out mouth with copious amounts of water; call a physician.

Inhalation: Remove from exposure and move to fresh air immediately.

5. Emergency Overview

Major Health Hazards: No major health hazards are known.

6. Fire Fighting Measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds

Fire Fighting Procedures: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

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7. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

8. Handling and Storage

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

Storage Conditions: Store as directed by product packaging.

9. Exposure Controls/Personal Protection

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

10. Physical Properties

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Appearance:

75 mg: White to light yellow colored blend filled in Size "2" capsule having Light blue opaque cap imprinted "MD" and Yellow opaque body imprinted "75" with black ink.
 110 mg: White to light yellow colored blend filled in Size "1" capsule having Light blue opaque cap imprinted "MD" and Yellow opaque body imprinted "110" with black ink.
 150 mg: White to light yellow colored blend filled in Size "0" capsule having Light blue opaque cap imprinted "MD" and Yellow opaque body imprinted "150" with black ink.

11. 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

12. Toxicological Information

- **Acute toxicity:** none known
- **Primary irritant effect:** not known
- **On the skin:** none known
- **On the eye:** not known; may be an irritant

13. Ecological Information

Dispose of in accordance with prevailing country, federal, state and local regulations.

14. Disposal Considerations

Dispose of in accordance with prevailing country, federal, state and local regulations.

15. Transport Information

IATA No information available.
 IMO No information available.
 ID/ADR No information available.

16. Regulatory Information

National legislation/regulations
 Water hazard class: VVWS
 WGK 1 slightly water endangering

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17. Other Information

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