

1. Identification of the substance/mixture and of the company/undertaking

Designation	: Pradaxa® 150 mg and 75 mg Capsules
Synonyms	: Active ingredient: Dabigatran Etexilate Pradaxa® capsules
Identified uses	: Pharmaceutical Product
Company	: Boehringer-Ingelheim Pharmaceuticals, Incorporated 900 Ridgebury Road Ridgefield, Connecticut 06877-0368
Emergency Contact Number	: 800-424-9300 CHEMTREC Emergency Phone Number
Routine Contact Number	: (203) 778-7759

2. Hazards 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 labeled according to EC-Directive 1999/45/EC, as amended.

3. Composition/Information on Ingredients
Hazardous ingredients

Chemical name	Classification	GHS classification	Concentration
N-[[2-[[[4-[[[(Hexyloxy)carbonyl]amino]imino]methyl]phenyl]amino]methyl]-1-methyl-1H-benzimidazol-5-yl]carbonyl]-N-pyridinyl-β-alanine ethylester Methansulfonate			2%
Molecular formula:	C ₃₄ H ₄₁ N ₇ O ₅ -CH ₄ O ₃ S	CAS-No.	593282-20-3
Molecular weight:	723,86		

Chemical name	Classification	GHS classification	Concentration
Non-hazardous galenic excipients			98%

4. First-aid Measures

- 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.
- Eye contact : Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.
- Skin contact : Wash off thoroughly with ample water. Seek medical attention.
- Inhalation : Keep patient calm, remove to fresh air, and seek medical attention.
- Ingestion : Rinse mouth immediately and then drink plenty of water, seek medical attention.

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.

6. Accidental Release Measures

- Personal precautions : Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation.
- Environmental precautions : Do not discharge into drains/surface waters/groundwater.
- 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.
- Additional information : Never return spills in original containers for re-use.

7. Handling and Storage**Handling**

- Advice on safe handling : 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.
- Hygienic measures : 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

- Requirements for storage rooms and vessels : Store in original container. Protect from heat and direct sunlight. Jointless smooth floor Keep container tightly closed.
- Further information : Keep at temperature not exceeding 25 °C.
- Advice on storage compatibility : Keep away from food, drink and animal feeding stuffs. Advice on Segregation

Storage class according to VCI : 11 Combustible Solids

8. Exposure controls/personal protections

Personal protective equipment

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.

9. Physical and Chemical Properties

Form : solid
Color : Yellow-white to yellow powder.
Odor : No data available.
Odor threshold : No data available.
pH value : No data available.
Melting point/ -range : No data available.
Boiling point/boiling range : not applicable
Flash point : not applicable
Ignition temperature : No data available.
Evaporation rate : No data available.
Flammability : No data available.
Lower explosion limit : No data available.
Upper explosion limit : No data available.
Vapor pressure : not applicable
Relative vapor density : No data available.
Relative density : No data available.
Solubility in water : partly soluble
Partitioning coefficient n-octanol/water (log Pow) : No data available.
Thermal decomposition : No data available.
Explosiveness : No data available.
Peroxides : No data available.
Minimum ignition energy : No data available.

10. Stability and Reactivity

Conditions to avoid : No data available.
Substances to avoid : No data available.

Hazardous decomposition products : No data available.

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.

12. Ecological information

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.

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.

13. Disposal Considerations

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.

14. Transport Information

Further information : Not classified as dangerous in the meaning of transport regulations. For the internal transport: Use only released containers. Use only tightly closed containers. The container must be correctly labeled. Protect container against fall down.

15. Regulatory information

National legislation/regulations

Water hazard class : VwVWS
WGK 1 slightly water endangering
Annex 4 VwVWS (Germany) dated Mai, 17 th 1999

16. Other particulars

Prepared by: Environmental Health & Safety
Date Prepared: March 30, 2012

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