

Release : 3.0
 Reviewed on : 08.03.2013
 Replaces the version of : 08.12.2011
 Date of Print : 18.11.2013
 Product : Pradaxa® solid (Bulk), <= 40%

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

Designation : **Pradaxa® solid (Bulk), <= 40%**

Synonyms : Active ingredient: Dabigatran Etexilate
Pradaxa® capsules

Identified uses : Mixture for production of finished medicinal products.

Company : Boehringer Ing. Pharma GmbH & Co.KG
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Information providing division : Quality & Environmental Health & Safety

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2. Hazards Identification

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.

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 | | | <= 40% |
| Molecular formula: | C35-H45-N7-O8-S | CAS-No. | 593282-20-3 |
| Molecular weight: | 723,86 | | |

| Chemical name | Classification | GHS classification | Concentration |
|----------------------------------|----------------|--------------------|---------------|
| Non-hazardous galenic excipients | | | >= 60% |

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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 : Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.
- Skin contact : Wash off immediately with plenty of water. Cover wound with sterile dressing. Call a physician immediately.
- Inhalation : Move to fresh air. Call a physician immediately.
- Ingestion : Rinse mouth. Drink plenty of water. Call a physician immediately.

Notes to physician

- Treatment : Observe the summary of product characteristics of proprietary medicinal products
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5. Fire-fighting Measures

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment., Water, Dry chemical, Foam, Carbon dioxide (CO₂)
- 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 (NO_x), Sulphur oxides
- Protective equipment for fire-fighting : Self-contained breathing apparatus (EN 133) complete suit protecting against chemicals
- Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
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6. Accidental Release Measures

- Personal precautions : Wear personal protective equipment. Ensure adequate ventilation. Refer to protective measures listed in sections 7 and 8. Keep people away from and upwind of spill/leak.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- 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.
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7. Handling and Storage

Handling

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Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms. Breathing must be protected when large quantities are decanted without local exhaust ventilation. Keep container closed when not in use.

Hints for protection against fire and explosion : Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Avoid dust formation.

Hygienic measures : General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

Storage

Requirements for storage rooms and vessels : Keep tightly closed in a dry and cool place. Keep in a well-ventilated place. Protect from heat and direct sunlight. Jointless smooth floor

Further information : Keep at temperature not exceeding 25 °C.

Advice on storage compatibility : Keep away from food, drink and animal feedingstuffs. Advice on Segregation

Storage class according to VCI : 11 Combustible Solids

8. Exposure controls/personal protections

Exposure controls

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required. Respirator must be worn if exposed to dust. half mask (EN 140) particle filter P2 (EN 143)

Hand protection : Chemical resistant protective gloves (EN 374)

Eye protection : Safety glasses with side-shields conforming to EN166

Body protection : Laboratory: laboratory coat; factory: chemical protection overall if dust is formed.

Additional information : Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

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

Colour : white

Odour : No data available.

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Odour 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.
Vapour pressure : not applicable
Relative vapour 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.

Further information

Minimum ignition energy : No data available.

10. Stability and Reactivity

Hazardous reactions : Accumulation of fine dust may entail the risk of a dust explosion in the presence of air.
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 > 2.000 mg/kg rat
The values mentioned are those of the active ingredient.
Acute inhalation toxicity : No data available.

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Acute dermal toxicity : No data available.

Repeated dose toxicity : rat
NOAEL: 10 mg/kg
Exposition time: 26 weeks The values mentioned are those of the active ingredient.
(BIBR 1048 MS)

monkey
NOAEL: 36 mg/kg
Exposition time: 52 weeks The values mentioned are those of the active ingredient.
(BIBR 1048 MS)

Skin irritation : Non-irritant (rabbit)
The values mentioned are those of the active ingredient.

Eye irritation : No data available.

Sensitization : Did not cause sensitisation 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: 15 mg/kg
NOAEL F1-Generation: 70 mg/kg
The values mentioned are those of the active ingredient.(BIBR 1048 MS)

Study for Effects on Embryo-Fetal Development
rabbit
NOAEL Parents: 200 mg/kg
NOAEL F1-Generation: < 15 mg/kg
The values mentioned are those of the active ingredient.

Teratogenicity : No data available.

Aspiration hazard : No data available.

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12. Ecological information

Ecotoxicity

Toxicity to fish : No data available.
Toxicity to daphnia : EC50 > 100 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

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Further information : Not classified as dangerous for conveyance in the meaning of the regulations for the transport of dangerous goods by road and rail. Not classified as dangerous in the meaning of sea and air transport regulations.

15. Regulatory information

National legislation/regulations

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

16. Other particulars

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.