

## 1. Identification

<b>Product identifier</b>	<b>Dabigatran Etexilate Mesilate</b>
<b>Other means of identification</b>	None.
<b>Recommended use</b>	Active pharmaceutical ingredient.
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	Boehringer Ingelheim Vetmedica, Inc.
<b>Address</b>	2621 North Belt Hwy St. Joseph, MO 64506-2002
<b>Transportation emergency</b>	For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 Outside USA and Canada: +1 703-527-3887 (collect calls accepted) (866)638-2226
<b>Medical Emergency (24HR):</b>	(866)638-2226
<b>Non-Emergency calls:</b>	(800) 821-7467

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Combustible dust
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	Warning
<b>Hazard statement</b>	May form combustible dust concentrations in air.
<b>Precautionary statement</b>	
<b>Prevention</b>	Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials. Store below 86°F (30°C).
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.

## 3. Composition/information on ingredients

### Mixtures

<b>Chemical name</b>	<b>CAS number</b>	<b>%</b>
N-[[2-[[[4-[[[(HEXYLOXY)CARBONYL]AMINO]IMINO-METHYL]PHENYL]AMINO]METHYL]-1-METHYL-1H-BENZIMIDAZOL-5-YL]CARBONYL]-N-PYRIDINYL-BETA-ALANINETHYLESTER METHANSULFONAT	593282-20-3	100

## 4. First-aid measures

<b>Inhalation</b>	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Dusts may irritate the respiratory tract, skin and eyes.
<b>Indication of immediate medical attention and special treatment needed</b>	Not for human use. For use in animals only. Treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). Apply extinguishing media carefully to avoid creating airborne dust.
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	May form combustible dust concentrations in air.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.  Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Minimize dust generation and accumulation. Avoid prolonged exposure. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Recommended storage temperature: 25°C Keep away from food, drink and animal feeding stuffs.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	PEL	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.

## US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	TWA	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

## US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Dust	TWA	3 mg/m <sup>3</sup>	Respirable particles.
		10 mg/m <sup>3</sup>	Inhalable particles.

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Not generally required when handling vials or containers. Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Skin protection</b>	
<b>Hand protection</b>	Wear protective gloves.
<b>Other</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Color</b>	Light yellow.
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	Not available.
<b>pH</b>	3 at 1.8 g/l
<b>Melting point/freezing point</b>	339.8 - 352.4 °F (171 - 178 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Combustible dust.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.

Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
<b>Solubility(ies)</b>	
Solubility (water)	1.8 g/l
Partition coefficient (n-octanol/water)	3.6 as log Pow at pH = 7
Auto-ignition temperature	869 °F (465 °C)
Decomposition temperature	Not available.
Viscosity	Not available.

## 10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Keep away from heat, sparks and open flame. Minimize dust generation and accumulation. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.

**Symptoms related to the physical, chemical and toxicological characteristics**      Dusts may irritate the respiratory tract, skin and eyes.

### Information on toxicological effects

Acute toxicity	This product is considered nontoxic.
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
<b>Respiratory or skin sensitization</b>	
Respiratory sensitization	Not a respiratory sensitizer.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	
Not listed.	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	Prolonged inhalation may be harmful.

## 12. Ecological information

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available.
<b>Partition coefficient n-octanol / water (log Kow)</b> Dabigatran Etexilate Mesilate	3.6, as log Pow at pH = 7
<b>Mobility in soil</b>	The product is slightly soluble in water. Expected to be slightly to moderately mobile in soil.
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not available.

## 15. Regulatory information

<b>US federal regulations</b>	One or more components are not listed on TSCA. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not listed.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>Hazard categories</b>	Immediate Hazard - No Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance</b>	Not listed.
<b>SARA 311/312 Hazardous chemical</b>	Yes
<b>SARA 313 (TRI reporting)</b>	Not regulated.

## Other federal regulations

### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

### Safe Drinking Water Act (SDWA)

Not regulated.

## US state regulations

### US. Massachusetts RTK - Substance List

Not regulated.

### US. New Jersey Worker and Community Right-to-Know Act

Not listed.

### US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

### US. Rhode Island RTK

Not regulated.

### US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

**Issue date** 06-May-2015

**Revision date** -

**Version #** 01

**Further information** Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

**HMIS® ratings** Health: 1  
Flammability: 1  
Physical hazard: 0

**NFPA ratings**



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