



Material Safety Data Sheet

N-[2-[4-[N-(Hexyloxycarbonyl)amidino]phenylaminomethyl]-1-methyl-1H-benzimidazol-5-ylcarbonyl]-N-(2-pyridyl)-beta-alanine ethyl ester

CAS No. 211915-06-9

Section 1 - Chemical Product and Company Identification

Common Name:	N-[2-[4-[N-(Hexyloxycarbonyl)amidino]phenylaminomethyl]-1-methyl-1H-benzimidazol-5-ylcarbonyl]-N-(2-pyridyl)-beta-alanine ethyl ester	Contact Information:	Manus Akteva Biopharma LLP 303, 3rd Floor, Royal Manor, Law Garden, Ellisbridge, Ahmedabad 380006, Gujarat, India.
Synonyms:	Dabigatran etexilate	For emergency, call:	Tel: + 91 79 26463395, 26463394 Fax: + 91 79 26463395
IUPAC Name:	Not Available	Email:	hello@manusaktevabiopharma.com products@manusaktevabiopharma.in
Molecular Formula:	C34H41N7O5		
Molecular Weight:	627.74		
CAS No.:	211915-06-9		
HS CODE:	Not Available		

Section 2: Composition/information on Ingredients

Composition

Principle Components	CAS #	Chemical Name	Transport Information
N-[2-[4-[N-(Hexyloxycarbonyl)amidino]phenylaminomethyl]-1-methyl-1H-benzimidazol-5-ylcarbonyl]-N-(2-pyridyl)-beta-alanine ethyl ester	211915-06-9	Dabigatran etexilate	Not Available

Section 3. Hazards identification, including emergency overview

Risk phrases: Toxic if swallowed-Harmful to aquatic organism.

Adverse human health effects: Changes in blood pressure. Exposure may produce an allergic reaction. May produce irregular heart beat and nervous symptoms. Headache. Dizziness.

Potential Health Effects Very hazardous in case of skin contact (irritant), of eye contact (irritant).

Hazardous in case of skin contact of ingestion, of inhalation (lung irritant). Slightly hazardous in case of skin contact (corrosive). Inflammation of the eye is characterized by redness, watering, and itching. Skin inflammation is characterized by itching, scaling, reddening, or, occasionally, blistering.

Section 4. First aid measures

Environment:

No information is available about the potential of this product to produce adverse environmental effects.

Ingestion: Do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

Inhalation: Allow the victim to rest in a well ventilated area. Seek immediate medical attention.

NOTES TO HEALTH PROFESSIONALS:

Medical Treatment:

Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information Centre. Medical treatment in cases of overexposure should be treated as an overdose and the target organs being nerves, treat it under expert medical advice and supervision.

Section 5. Firefighting measures

Flammability of the Product: No May be combustible at high temperature

Flash Point: Not Available

Products of Combustion: Not Available.

Auto ignition Temperature: Not applicable.

Explosion Limits, Lower: Not available.

Explosion Hazards in presence of various substances: Risks of explosion of the product in presence

General Information:

As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

Extinguishing Media:

In case of fire, use water, dry chemical, chemical foam, or alcohol-resistant foam. Use firefighting measures which suit the environment and take into account other materials which may be involved. In general, water-based extinguishers should not be used for fires involving organic materials. Use carbon dioxide or dry powder.

Section 6. Accidental release measures

Personal Precautions:

Splash goggles, Full suit, Dust respirator, Boots, Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product

Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7. Handling and storage

Precautions: Keep container dry. Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk; evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe gas/fumes/ vapor/spray. Never add water to this product In case of insufficient ventilation, wear suitable respiratory equipment If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes

Handling: Handle in accordance with good industrial hygiene and safety procedures

Storage: Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.

Section 8. Exposure controls/personal protection

Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protective Equipment:

Eyes: Wear safety glasses and chemical goggles if splashing is possible.

Skin: Wear appropriate protective gloves and clothing to prevent skin exposure.

Clothing: Wear appropriate protective clothing to minimize contact with skin.

Respirators: Wear a NIOSH/MSHA or European Standard EN 149 approved full-face piece airline respirator in the positive pressure mode with emergency escape provisions.

Exposure Limits: Not available.

Section 9. Physical and chemical properties protection

Product Name: N-[2-[4-[N-(Hexyloxycarbonyl)amidino]phenylaminomethyl]-1-methyl-1H-benzimidazol-5-ylcarbonyl]-N-(2-pyridyl)-beta-alanine ethyl ester

CAS No: 211915-06-9

Physical state and appearance: Not Available.

Odor: Not Available.

Molecular Weight: 627.74

Color: Not Available

Vapor Density: Not Available

Molecular Formula: C₃₄H₄₁N₇O₅

Dispersion Properties: Not Available

Solubility: Not Available

pH (1% solution/water): Not available.

Boiling Point: Not Available

Freezing/Melting Point: Not Available

Specific Gravity: Not Available

Auto ignition Temperature: Not available.

Flash Point: Not Available

Section 10. Stability and Reactivity

Chemical Stability: Stable under normal temperatures and pressures. Stable at room temperature in closed containers under normal storage and handling conditions.

Stability: The product is stable.

Conditions to Avoid: Sources of ignition. Light, Heat.

Incompatibilities with various substances: Bases- oxidizing agents and reducing agents .

Polymerization:No

Hazardous Decomposition Products: CO₂, CO.

Hazardous reactions: None under normal conditions.

Hazardous polymerization: Will not occur.

Section 11. Toxicological information

Product Name: N-[2-[4-[N-(Hexyloxycarbonyl)amidino]phenylaminomethyl]-1-methyl-1H-benzimidazol-5-ylcarbonyl]-N-(2-pyridyl)-beta-alanine ethyl ester

CAS No: 211915-06-9

Routes of Entry: Dermal contact. Eye contact. Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): Not Available

Chronic Effects on Humans: Not listed by ACGIH, IARC, NIOSH, or OSHA.

Other Toxic Effects on Humans: Not Available

Special Remarks on Toxicity to Animals: Not Available

Special Remarks on Chronic Effects on Humans: passes through the placenta, excreted in maternal milk.

Special Remarks on other Toxic Effects on Humans: Not Available

RTECS#: **Product Name:** N-[2-[4-[N-(Hexyloxycarbonyl)amidino]phenylaminomethyl]-1-methyl-1H-benzimidazol-5-ylcarbonyl]-N-(2-pyridyl)-beta-alanine ethyl ester, CAS NO 211915-06-9 unlisted.

Carcinogenicity: CAS NO 211915-06-9 Not listed by ACGIH, IARC, NTP, or CA Prop 65.

Effects of Acute Exposure: Data not available

Effects of Chronic Exposure: Data not available

Irritancy of Product: Data not available

Skin Sensitization: Data not available

Respiratory Sensitization: Data not available

Carcinogenicity-IARC: Data not available

Carcinogenicity - ACGIH: Data not available

Reproductive Toxicity: Data not available

Teratogenicity: Data not available

Embryo toxicity: Data not available

Mutagenicity: Data not available

Name of Synergistic Products / Effects: Data not available

Section 12. Ecological information

Eco toxicity: Not Available.

BOD5 and COD: Not Available.

Products of Biodegradation: Not Available

Toxicity of the Products of Biodegradation: Not Available

Special Remarks on the Products of Biodegradation: Not available.

Section 13. Disposal considerations

Disposal Recommendations

Dispose of in a manner consistent with federal, state, and local regulations. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

RCRA P-Series: None listed.

RCRA U-Series: None listed.

Section 14. Transport information

This section provides guidance on classification information for shipping and transporting of Hazardous chemical(s) by road, air, rail, or sea. The information may include:

Transport hazard class(es): Not Available

US DOT

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UN Number: Not Available

Packing Group: Not Available

DOT Classification: Not Available

Hazard Class: Not Available

Environmental hazards: Not Available

UN proper shipping name: N-[2-[4-[N-(Hexyloxycarbonyl)amidino]phenylaminomethyl]-1-methyl-1H-benzimidazol-5-ylcarbonyl]-N-(2-pyridyl)-beta-alanine ethyl ester

IMDG:

Product Name: N-[2-[4-[N-(Hexyloxycarbonyl)amidino]phenylaminomethyl]-1-methyl-1H-benzimidazol-5-ylcarbonyl]-N-(2-pyridyl)-beta-alanine ethyl ester, CAS NO 211915-06-9

UN Number: Not Available

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DOT Classification: Not Available

Hazard Class: Not Available

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IATA:

Product Name: N-[2-[4-[N-(Hexyloxycarbonyl)amidino]phenylaminomethyl]-1-methyl-1H-benzimidazol-5-ylcarbonyl]-N-(2-pyridyl)-beta-alanine ethyl ester, CAS NO 211915-06-9

UN Number: Not Available

Packing Group: Not Available

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Hazard Class: Not Available

Environmental hazards: Not Available

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Section 15. Regulatory information

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols: Not Available

UN Number: Not Available

Packing Group: Not Available

Risk Phrases: R 22,36,37 Harmful if swallowed, Irritating to eyes, respiratory system

Safety Wear suitable protective clothing, **S 24/25** Avoid contact with skin and eyes.
S 37 Wear suitable gloves, **S 45** In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S 28A after contact with skin wash immediately with plenty of water

United Kingdom Occupational Exposure Limits ,United Kingdom Maximum Exposure Limits

CAS NO 211915-06-9 is listed on **EINECS Master Inventory list**

Exposure Limits

US FEDERAL TSCA CAS NO 211915-06-9 is not noticed by us on TSCA list.

CAS NO 211915-06-9 is listed on EINECS Master Inventory list

Section 16. Other information

The information above is believed to be accurate and represents the best information currently available to us. However, **MANUS AKTEVA BIOPHARMA LLP** make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no way shall **MANUS AKTEVA BIOPHARMA LLP** be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

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