

**SAFETY DATA SHEET**

Print date March 9, 2020

**Section 1. Identifications**

Product name: Dabigatran Etexilate Impurity 3

TLC ID: D-5927

Product Use: For laboratory use only. Not for use in humans or animals, drug, household or other use.

Supplier/Manufacturer:

**TLC Pharmaceutical Standards Ltd.**

130 Pony Drive

Newmarket, ON, L3Y 7B6, Canada

Telephone: (905)-898-3645 Fax: (905)-898-0595

Website: www.tlcstandards.com

**Section 2. Hazards identifications**

Physical state: Solid

Warning: Harmful if swallowed, inhaled or in contact with skin.

Routes of entry: Inhalation, skin, eyes

**GHS classification:**

Skin irritation (Category 2)

Serious eye damage/eye irritation (Category 2)

Acute toxicity, oral (Category 4)

Acute toxicity, dermal (Category 4)

Acute toxicity, inhalation (Category 4)

**GHS Label elements, including precautionary statements**

Pictogram(s):



Signal word: Warning

Hazards statements:

H302 +H312 +H332 Harmful if swallowed, in contact with skin or if inhaled.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: wash with plenty of soap and water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**Section 3. Composition/ Information on Ingredients**

CAS No.: 1416446-43-9

Molecular Formula: C<sub>32</sub>H<sub>37</sub>N<sub>7</sub>O<sub>5</sub>

Molecular Weight: 599.69

Synonyms: ethyl

3-(2-(((4-(N-(butoxycarbonyl)carbamimidoyl)phenyl)amino)methyl)-1-methyl-N-(pyridin-2-yl)-1H-benzo[d]imidazole-5-carboxamido)propanoate

## **Section 4. First-aid measures**

### **General**

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

### **If inhaled**

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

### **In case of eye contact**

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

### **In case of skin contact**

Wash off with soap and plenty of water. Consult a physician.

### **If swallowed**

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

## **Section 5. Firefighting measures**

### **Conditions of flammability**

Not flammable or combustible.

### **Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

### **Hazardous combustion products**

Hazardous decomposition products formed under fire conditions: carbon oxides, sodium oxides, nitrogen oxides

### **Special firefighting procedures**

Wear self-contained breathing apparatus and protective clothing.

## **Section 6. Accidental release measures**

### **Personal precautions**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

### **Environmental precautions**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Method and materials for containment and cleaning up

### **Method and materials for containment and cleaning up**

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

## **Section 7. Handling and storage**

### **Handling**

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Keep away from sources of ignition. Take measures to prevent the buildup of electrostatic charge.

### **Storage**

Keep refrigerated as specification of Certificate of Analysis. Keep container tightly closed in a dry and well-ventilated place.

## Section 8. Exposure controls/personal protection

### *Engineering controls*

Use mechanical exhaust or laboratory fumehood to avoid exposure.

### *Personal protective equipment*

#### **Respiratory protection**

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

#### **Hand Protection**

Handle with chemical-resistant gloves, solvent-resistant gloves. Gloves must be inspected prior to use. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

#### **Eye Protection**

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

#### **Skin and body protection**

Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

## Section 9. Physical and chemical properties

**Physical property:** Solid

**Colour:** Pale yellow

**Odour:** No data available

**Density:** No data available

**Melting Point/Freezing Point(°C):** No data available

**Flash Point (°C):** No data available

**Explosive Properties:** No data available

**Oxidizing Properties:** No data available

**Water solubility:** No data available

**Solubility (other solvents):** Methanol, DMSO, DMF, Acetonitrile

## Section 10. Stability and reactivity

**Reactivity:** No data available.

**Chemical stability:** Stable under recommended storage conditions.

**Conditions to avoid:** Heat, flames and sparks. Extremes of temperature and direct sunlight.

**Materials to avoid:** oxidizing agents.

**Hazardous decomposition products:** possible products formed under fire conditions: Carbon oxides.

## Section 11. Toxicological information

### *Acute toxicity*

**Oral LD50:** No data available. Inhalation.

**LC50:** No data available.

**Dermal LD50:** No data available.

**Skin Corrosion/Irritation:** Toxic if absorbed through skin. May cause skin irritation.

**Eyes:** May cause eye irritation.



Acute and Chronic Health hazards: TLV: None verified.

Effects of Overexposure: May causes eye, respiratory, and skin irritation. May be harmful by inhalation, ingestion, or skin absorption.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated

## **Section 12. Ecological information**

No data available.

## **Section 13. Disposal considerations**

### **Product**

Burn in a chemical incinerator equipped with an afterburner and scrubber but exert extra care in igniting as this material is highly flammable. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

### **Contaminated packaging**

Dispose of as unused product.

## **Section 14. Transport information**

Non-hazardous for transport. IATA - Not regulated

## **Section 15. Regulatory information**

TLV: None verified

## **Section 16. Other information**

This product is not bioactive, not radioactive. It is for R&D use only. Not for drug, household or other uses.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. TLC Pharmaceutical Standards Ltd. extends no warranties with respect hereto and disclaims all liabilities from reliance thereon. All judgments as to the suitability of the data presented with respect to the use of this product are the responsibility of the purchaser and intended user.