

Material Safety Data Sheet

Revision Date: 6/15/2024

1. IDENTIFICATION OF SUBSTANCE:

Trade name: BIBR-1048 (Dabigatran etexilate)

Catalog Number: C2104

Manufacturer/Supplier: **Cellagen Technology LLC**

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2. COMPOSITION/DATA ON COMPONENTS:

Chemical Name: (E)-ethyl 3-(2-((4-(N'-(hexyloxycarbonyl)carbamimidoyl)phenylamino)methyl)-1-methyl-N-(pyridin-2-yl)-1H-benzo[d]imidazole-5-carboxamido)propanoate

Synonyms: BIBR 1048, BIBR1048, BIBR-1048, Dabigatran, Pradaxa

Hazardous Ingredient: BIBR-1048 (Dabigatran etexilate)

CAS Registry Number: 211915-06-9

Molecular Weight: 627.73

Molecular Formula: $C_{34}H_{41}N_7O_5$

3. HAZARDS IDENTIFICATION:

Hazard Description: Substance not fully tested

May be harmful if swallowed or inhaled. Exposure may cause irritation of the respiratory tract, eye, and skin and allergic respiratory and skin reaction. Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients.

4. FIRST AID MEASURES:

After Inhalation: If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give

After skin contact: flush with copious amounts of water; remove contaminated clothing and shoes; call a

After eye contact: check for and remove contact lenses; flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician

After swallowing: if swallowed, wash out mouth with copious amounts of water; call a physician

5. FIRE FIGHTING MEASURES:

Suitable extinguishing agents: Small fires by using dry chemical powder. ABC fire extinguishers; Large fires by using water spray, fog or foam.

Protective equipment: wear self-contained breathing apparatus and protective clothing to prevent contact with

6. ACCIDENTAL RELEASE MEASURES:

Person-related safety precautions: cordon off area of spill; wear self-contained breathing apparatus, protective clothing and heavy rubber gloves.

Measures for cleaning/collecting: absorb solutions with finely- powdered liquid-binding material (diatomite, universal binders); decontaminate surfaces and equipment by scrubbing with alcohol; dispose of contaminated

7. HANDLING AND STORAGE:

Information for safe handling: Handle with care and avoid unnecessary exposure. Avoid inhalation.

Avoid contact with eyes, skin, and clothing. Use protective equipment to minimize exposure. Avoid prolonged or repeated exposure. Handle compound in a laboratory fume hood.

Storage: store solid and solutions at 4°C or -20°C for longer time storage.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION:

Engineering controls: safety shower and eye bath; mechanical exhaust required.

Personal protective equipment as follows:

Breathing equipment: NIOSH/MSHA-approved respirator.

Protection of hands: chemical-resistant rubber gloves.

Eye protection: chemical safety goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Form: Powder or crystalline solid

Color: white

Odor: None

Danger of explosion: None

Solvent content: None

Solubility: DMSO

10. STABILITY AND REACTIVITY:

Stability: Stable

Conditions to avoid: Protect from light and heat

Material to avoid: Acids and bases

Dangerous products of decomposition: thermal decomposition may produce toxic gases such as carbon monoxide, carbon dioxide, and nitrogen oxides

11. TOXICOLOGICAL INFORMATION:

RTECS No: not available

Acute toxicity: not known

Primary irritant effect: not known

On the skin: not known; may be an irritant

On the eye: not known; may be an irritant

Effects of Short-Term Exposure: not available

Effects of Long-Term Exposure: not available

Sensitization to Product: not available

Carcinogenicity: not available

Reproductive Toxicity: not available

Teratogenicity and Embryotoxicity: not available

Mutagenicity: not available

12. ECOLOGICAL INFORMATION:

Ecotoxicity: not known

13. DISPOSAL CONSIDERATION:

Dispose of in accordance with prevailing country, federal, state and local regulations

14. TRANSPORT INFORMATION:

DOT:

Proper shipping name: none

Non-Hazardous for transport: this substance is considered to be non-hazardous for transport

IATA class:

Proper shipping name: none

Non-Hazardous for transport: this substance is considered to be non-hazardous for transport

15. REGULATIONS:

U.S. Federal Regulations

- SARA 313: Not SARA listed
- Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see CFR 61): No products were found.

U.S. State Regulations

- California Proposition 65: No products were found.

WHMIS Hazard Class: Not controlled under WHMIS (Canada)

16. OTHER INFORMATION:

The above information is believed to be correct based on our present knowledge but does not purport to be complete. For research use only by trained personnel. The burden of safe use of this material rests entirely with the user. Cellagen Technology disclaims all liability for any damage resulting from use of this material. For research use only. Not for use in diagnostic or therapeutic applications.

END OF SAFETY DATA SHEET