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**BioMed**

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pour le diagnostic biomédical...

# MATERIAL SAFETY DATA SHEET

**Product name: BIOPHEN<sup>®</sup> RIVAROXABAN CALIBRATOR LOW, BIOPHEN<sup>®</sup> RIVAROXABAN CONTROL LOW**

**Product reference: D730-05-BI-6001-5101**

## **Summary**

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**MATERIAL SAFETY DATA SHEET**

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**ENGLISH****SECTION 1: PRODUCT & COMPANY IDENTIFICATION****1.1. Product identifier**

| Name                                | number |
|-------------------------------------|--------|
| BIOPHEN® RIVAROXABAN CALIBRATOR LOW | 226001 |
| BIOPHEN® RIVAROXABAN CONTROL LOW    | 225101 |

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

The product must be used according strictly to the instructions of package insert, and for the indicated purpose.

**1.3. Details of the manufacturer and supplier of the safety data sheet**

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155 rue d'Eragny  
95000 Neuville sur Oise (France)

Tel: 33.1.34.40.65.10

Fax: 33.1.34.48.72.36

E-mail address: [info@hyphen-biomed.com](mailto:info@hyphen-biomed.com)**1.4. Emergency telephone number**

Tel: 33.1.34.40.65.10

**SECTION 2: HEALTH HAZARDS IDENTIFICATION****2.1. Classification of the substance or mixture****Classification information**

This product does not meet the classification and labelling criteria given in the Dangerous Preparations Directive 1999/45/EC.

**2.2. Label elements**

Biohazard

**2.3. Other hazards****PBT assessment**

No data available.

**vPvB assessment**

No data available.

## SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

### 3.1. Substances

Not applicable the product is not a substance

### 3.2. Mixtures

#### **Hazardous ingredients**

This product does not contain substances to be mentioned according to EU Regulation No 1272/2008 or UE 67/548/CEE and 1999/45/CE.

### 3.3. Other information

Do not inject or ingest.

All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B( HBsAg), negative by tests for antibodies to HIV (HIV-1/HVI-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA, and non-reactive to Serological Test for Syphilis (STS). Because no known test method can assure complete absence of pathogens this product should be handled with appropriate precautions.

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

#### **General information**

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

#### **After inhalation**

Removed affected person from the immediate area. Ensure supply of fresh air.

#### **After skin contact**

Wash off immediately with soap and water.

#### **After eye contact**

Separate eyelids; wash the eyes thoroughly with water (15 min).

#### **After ingestion**

Summon a doctor immediately. Do not induce vomiting. Never give anything by mouth to an unconscious person.

### 4.2. Most important symptoms and effects, both acute and delayed

No data available.

### 4.3. Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5: FIRE AND EXPLOSION HAZARDS DATA

### 5.1. Extinguishing media

#### **Suitable extinguishing media**

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas

#### **Unsuitable extinguishing media**

No data available.

### 5.2. Special hazard arising from the substance or mixture

In the event of fire, the following can be released: Carbon dioxide (CO<sub>2</sub>); Carbon monoxide (CO)

### 5.3. Advice for firefighters

Use self-contained breathing apparatus. Wear protective clothing.

## SECTION 6: SPILL, LEAK AND DISPOSAL PROCEDURES

### 6.1. Personal protections, protective equipment and emergency procedures

#### For non-emergency personnel

Refer to protective measures listed in section 7 and 8. Avoid contact with skin, eyes and clothing.

#### For emergency responder

No data available. Personal protective equipment (PPE) – see section 8.

### 6.2. Environmental precautions

Do not discharge into the drains/surface water/groundwater. Do not discharge into the subsoil/soil.

### 6.3. Methods and material for containment and cleaning up

Take up with absorbent material. When picked up, treat material as prescribed under heading “Disposal considerations”.

## SECTION 7: CAUTIONS TO BE TAKEN IN HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Advice on safe handling

Product inherent handling risks must be minimised taking the appropriate measures for protection and preventive actions. The working process should be designed to rule out the release of hazardous substances or skin contact as far it is possible by state of the art.

#### General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Do not inhale vapours. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately.

#### Advice on protection against fire and explosion

No special measures necessary.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions

Keep container tightly closed. Store in refrigerator.

#### Recommended storage temperature

Value: 2 - 8°C

#### Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

### 8.1. Control parameters

No parameters available for monitoring.

### 8.2. Exposure controls

#### Appropriate engineering controls

No data available.

#### Personal protective equipment

##### Respiratory protection

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

##### Eye / face protection

Safety glasses (EN 166).

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## Hand protection

In case of intensive contact, wear protective gloves (EN 374). Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

## Other

Normal chemical work clothing.

## Environmental exposure controls

No data available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

| Property                               | Human citrated plasma with various concentrations of Rivaroxaban |
|--|--|
| Appearance                             | Lyophilised powder   |
| Odour                                  | None   |
| pH value                               | No data available.   |
| Boiling point                          | No data available.   |
| Melting point                          | No data available.   |
| Decomposition point                    | No data available.   |
| Flash point                            | No data available.   |
| Auto-ignition temperature              | No data available.   |
| Oxidising properties                   | No data available.   |
| Explosive properties                   | No data available.   |
| Flammability                           | No data available.   |
| Lower flammability or explosive limits | No data available.   |
| Upper flammability or explosive limits | No data available.   |
| Vapour pressure                        | No data available.   |
| Vapour density                         | No data available.   |
| Evaporation rate                       | No data available.   |
| Relative density                       | No data available.   |
| Solubility in water                    | No data available.   |
| Solubility                             | No data available.   |
| Partition coefficient: n-octano/water  | No data available.   |
| Viscosity                              | No data available.   |
| Other information                      | No data available.   |

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

No data available.

### 10.2. Chemical stability

No data available.

### 10.3. Possibility of hazardous reactions

No data available.

### 10.4. Conditions to avoid

No data available.

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## 10.5. Incompatible materials

None known.

## 10.6. Hazardous decomposition products

None, if handled according to order.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

| Effects                           | Human citrated plasma with various concentrations of Rivaroxaban |
|-----------------------------------|--|
| Acute oral toxicity               | No data available.   |
| Acute dermal toxicity             | No data available.   |
| Acute inhalational toxicity       | No data available.   |
| Skin corrosion/irritation         | No data available.   |
| Serious eye damage/irritation     | No data available.   |
| Respiratory or skin sensitisation | No data available.   |
| Germ cell mutagenicity            | No data available.   |
| Reproduction toxicity             | No data available.   |
| Carcinogenicity                   | No data available.   |
| Stot-single exposure              | No data available.   |
| Stot-repeated exposure            | No data available.   |
| Aspiration hazard                 | No data available.   |

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

| Toxicity          | Human citrated plasma with various concentrations of Rivaroxaban |
|-------------------|--|
| Fish toxicity     | No data available.   |
| Daphnia toxicity  | No data available.   |
| Algae toxicity    | No data available.   |
| Bacteria toxicity | No data available.   |

### 12.2. Persistence and degradability

No data available.

### 12.3. Bio-accumulative potential

No data available.

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

| Assessment      | Human citrated plasma with various concentrations of Rivaroxaban |
|-----------------|--|
| PBT assessment  | No data available.   |
| vPvB assessment | No data available.   |

### 12.6. Other adverse effects

No data available.

### 12.7. Other information

| Other information  |
|--|
| Do not discharge product unmonitored into the environment. |

## SECTION 13: WASTE DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Product

Allocation of a waste code number, according to the European waste catalogue, should be carried out in agreement with the regional waste disposal company.

#### Packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

## SECTION 14: TRANSPORT AND STORAGE INFORMATION

### 14.1. transport ADR/RID/AND

The product is not subject to ADR/RID/ADN regulations.

### 14.2. Transport IMDG

The product is not subject to IMDG regulations.

### 14.3. Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

### 14.4. Other information

No data available.

### 14.5. Environmental hazards

Information on environmental hazards, if relevant, pls. See 14.1 - 14.3.

### 14.6. Special precautions for user

No data available.

### 14.7. Transport in bulk according to annex II of MARPOL 73/78 and the IBC Code

Not relevant

## SECTION 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulations

This MSDS file is comply to the requirements described on the Regulation (EC) No 1907/2006 (REACH)

### 15.2. Chemical safety assessment

No data available.

## SECTION 16: OTHER INFORMATION

The information reported on this MSDS is believed to be accurate and represents the best information available to us. However, we make no warranty of merchantability or any other warranty, expressed or implied, with respect to such information, and we assure no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. HYPHEN BioMed and its appointed agents/distributors or OEM contractors shall not be held liable for any damage resulting from or from contact with the products included in the kit.