SECTION-1: Identification of the substance / mixture and the company / undertaking

1.1 Product identifiers

Product Name : Rivaroxaban EP Impurity B

Catalogue Number : CS-P-02086

Brand : Clearsynth Labs Ltd.

REACH No. : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

1.2 Relevent identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory Chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company : Clearsynth Labs Ltd.
17, Lotus Business Park,
New Link Road, Andheri (W),
Mumbai-400053, INDIA

1.4 Emergency telephone number

Emergency Phone # : +91-22-245045900

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Acute toxicity, oral,(Category 4), H302
Skin corrosion/irritation,(Category 2), H315
Serious eye damage/eye irritation,(Category 2A), H319
Specific target organ toxicity, single exposure; Respiratory tract irritation,(Category 3), H335

2.2 Label Elements

warning



Hazard Statement(s)

H302 Harmful if swallowed
H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation

Precautionary Statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338IF IN EYES: Rinse cautiously with water for several minutes.Remove contact lenses,if present and easy to do. Continue rinsing.

Other Hazards -

No data available

SECTION 3: Composition / information on ingredients

3.1 Mixtures

Molecular weight : 333.34 (g/mol)

Component	Classification	Concentration
Rivaroxaban EP Impurity B		
CAS Number : 1429334-00-8 **Molecular Formula** : $C_{16}H_{19}N_3O_5$ **EC - No.** :		

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of First Aid Measures

General Advice:

Consult a physician. Show this safety data sheet to the doctor in attendance.

If Inhaled:

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

In Case of Skin Contact:

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

In Case of Eye Contact:

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

If Swallowed:

Never give anything by mouth to an unconscious person.Rinse mouth with water.Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable Extinguishing Media

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

5.2 Special Hazards From Arising From Substance or mixture

During a fire,irritating & highly toxic gases may be generated by thermal decomposition or combustion.

5.3 Advice For Firefighters

Wear self-contained breathing appratus & full protective gear to prevent contact with skin & eyes.

5.4 Further information

Use water spray to cool unopened containers.

SECTION 6: Accidental release measures

6.1 Personal Precautions, Protective Equipment And Emergency Procedures

Wear respiratory protection. Avoid breathing vapours, mist or gas.

Ensure adequate ventilation. Remove all sources of ignition.

Evacuate personnel to safe areas.

Beware of vapours accumulating to form explosive concentrations.

Vapours can accumulate in low areas.

For personal protection see section 8.

6.2 Environmental Precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains or water sources.

6.3 Methods and materials for containment and cleaning up

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

6.4 Reference to other sections

For disposal see section 13.

SECTION-7: HANDLING AND STORAGE

7.1 Precautions For Safe Handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

Keep away from sources of ignition - No smoking.Take measures to prevent the build up of electrostatic charge.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Recommended storage temperature Store at refrigerator (2-8°C) for long term storage.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Components with workplace control parameters

8.2 Exposure controls

Appropriate Engineering Controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Personal Protective Equipment

Eyes / face 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 Protection :

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

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.

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).

Control of environmental exposure
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Physical State	:	Solid
b) Color	:	White
c) Odor	:	No data available
d) pH	:	No data available
e) Vapour Pressure	:	No data available
f) Viscosity	:	No data available
g) Inital Boiling Point and boiling range	:	No data available
h) Melting Point / Freezing Point	:	>181°C
i) Auto Ignition Temperature	:	No data available
j) Flash Point	:	No data available
k) Explosion Limit, Lower	:	No data available
l) Explosion Limit, Upper	:	No data available
m) Decomposition Temperature	:	No data available
n) Loss on Drying	:	No data available
o) Relative Density	:	No data available
p) Solubility	:	Soluble in DMSO
q) Oxidizing Properties	:	No data available

9.2 Other Safety Information

No Data Available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical Stability

Stable under recommended storage conditions.

10.3 Possibility of Hazardous reactions

No data available.

10.4 Condition to Avoid

Heat, flames and sparks. Extremes of temperature and direct sunlight.

10.5 Incompatibilities with Other Materials

Strong oxidizing agents, strong bases.

10.6 Hazardas Decomposition Products

No data available.

SECTION 11: Toxicological information

11.1 Information on Toxicological Effects

Acute Toxicity

Oral Rat LD50>11,500mg/kg

Skin Irritation/Corrosion

No data available

Eye Damage/Irritation

No data available

Respiratory or Skin Sensitization

No data available

Germ Cell Mutagenicity

No data available

Carcinogenicity

No data available

Reproductive Toxicity

No data available

Routes of Exposure

Inhalation, Eye contact, Ingestion, Skin contact.

Toxic Effects on Humans

No data available

Additional Information

No data available

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN Number :

DOT (US)	N/A
IATA	N/A
IMDG	N/A
ADR/RID	N/A

14.2 UN Proper Shipping Name :

DOT (US) / IATA	Not dangerous goods.
IMDG / ADR / RID	Not dangerous goods.

14.3 Transport Hazard Class (es) :

DOT (US)	N/A
IATA	N/A
IMDG	N/A
ADR/RID	N/A

14.4 Packing Group :

DOT (US)	N/A
IATA	N/A
IMDG	N/A
ADR/RID	N/A

14.5 Environmental Hazards :

DOT (US)	None
IATA	None
IMDG	None
ADR/RID	None

14.6 Special precautions for user

No data available

SECTION 15: Regulatory information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) :

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

---

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H302 Harmful if swallowed
H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation

Further Information

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. However, we 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 the company 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.