Safety Data Sheet

MyImatinib Calibrator and Control Kit

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Date of issue: 11-Jul-17

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

1.1. Product identifier

Product Form	: Mixture
Product Name	: MyImatinib Calibrator Kit : MyImatinib Control Kit
Product Code	: IM-CAL (Calibrator Kit) : IM-CON (Control Kit)

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

Industrial/Professional Use	: For Professional Use Only
Use of the Substance/Mixture	: In Vitro Diagnostic Medical Device

1.3. Details of the supplier of the safety data sheet

Manufacture	European Authorized Representative
Saladax Biomedical, Inc. 116 Research Dr. 18015 Bethlehem, PA T 610-419-6731 techsupport@saladax.com www.saladax.com	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands T +31 70 345 8570

1.4. Emergency telephone number

Emergency Number	: CHEMTREC 1-800-424-9300 (US or Canada);1-703-527-3887 (International)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

This substance is classified as not hazardous according to Regulation (EC) No. 1272/2008 [CLP].

2.2 Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

According to Regulation (EC) No. 1272/2008 [CLP], this product does not require labeling.

2.3 Other hazards

No additional information available.

SECTION 3: Composition/information on ingredients

3.1 Substance

Not applicable

3.2 Mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No. 1272/2008 [CLP].

SECTION 4: First aid measures

4.1 Description of first aid measures

General	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if breathing is irregular or stopped.
Skin Contact	: Remove/take off immediately all contaminated clothing. Rinse skin with water/shower. Wash with plenty of soap and water. Wash contaminated clothing before reuse. Call a POISON CENTER or doctor/physician in case of skin reaction.
Eye Contact	: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for 10-15 minutes. Obtain medical attention if pain, blinking or redness persists.
Ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER or doctor/physician if you feel unwell.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable Extinguishing Media	: The product itself does not burn. Coordinate fire-fighting measures to the fire surroundings.
Unsuitable Extinguishing Media	: No restrictions.

5.2 Special hazards arising from the substance or mixture

No specific hazards.

5.3 Advice for firefighters

No specific advice for firefighters.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General Measures	: Clean spills immediately with absorbent material and rinse the area with water.

6.1.1 For non-emergency personnel

Emergency Procedures	: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Personal Protective Equipment	: Refer to Section 8 of this SDS for appropriate personal protective equipment.
Emergency Procedures	: No specific emergency procedures.

6.2 Environmental precautions

No specific environmental precautions

6.3 Methods and material for containment and cleaning up

Clean spills with absorbent material. Rinse spill area with water.

6.4 Reference to other sections

Refer to sections 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective Measures	: Wear gloves when handling.
General Occupational Hygiene	: Do not eat, drink, or smoke when using this product. Wash hands thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage Conditions	: Keep in the original container. Store refrigerated at 2-8 °C.

7.3 Specific end use(s)

For *in vitro* diagnostic use only

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Does not contain substances above concentration limits requiring an occupational exposure limit.

8.2 Exposure controls

Personal Protective Equipment	: Avoid all unnecessary exposure. Wear safety glasses, gloves, protective clothing.
Hand Protection	: Wear protective gloves.
Eye Protection	: Wear chemical goggles or safety glasses.
Respiratory Protection	: No respiratory protection necessary.
Other Information	: Do not eat, drink, or smoke during use.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical State	: Liquid
Color	: Clear, Colorless
Odor	: Little or no odor
Odor Threshold	: No data available
pH	: 7.5
Relative Evaporation Rate	: No data available
Melting Point	: 0 °C
Boiling Point	: 100 °C

Flash Point	: Not applicable
Auto-ignition Temperature	: Not applicable
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: 24 mmHg
Relative Vapor Density at 20 °C	: No data available
Relative Density	: 1 g/cm^3
Solubility	: Miscible
Viscosity, Kinematic	: No data available
Viscosity, Dynamic	: No data available
Explosive Properties	: Not applicable
Oxidizing Properties	: Not applicable
Explosive Limits	: Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions.

10.4 Conditions to avoid

Stable under normal conditions.

10.5 Incompatible materials

No incompatible materials.

10.6 Hazardous decomposition products

No hazardous decomposition products.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute Toxicity	: Not classified (Based on available data, the classification criteria are not met)
Skin Corrosion / Irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious Eye Damage / Irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or Skin Sensitization	: Not classified (Based on available data, the classification criteria are not met)
Germ Cell Mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive Toxicity	: Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity Single Exposure	: Not classified (Based on available data, the classification criteria are not met)
Specific Target Organ Toxicity Repeated Exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration Hazard	: Not classified (Based on available data, the classification criteria are not met)

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

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste Disposal Recommendations : Dispose according to local / national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1 UN number

Not applicable

14.2 UN proper shipping name

Not applicable

14.3 Transport hazard class(es)

Not classified (Based on available data, the classification criteria are not met)

14.4 Packing group

Not classified (Based on available data, the classification criteria are not met)

14.5 Environmental hazards

Dangerous to the environment : No

Marine Pollutant : No

Other Information : No supplementary information available

14.6 Special precautions for user

No special precautions required

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1 EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2 National regulations

No additional information available

15.2 Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Other Information : None

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product