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MATERIAL SAFETY DATA SHEET (MSDS)

Revision Date 8/26/2019 Print Date 8/26/2019

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

MedK©©

Product name: **Icatibant** 314226 Product Catalogue Number:

Brand: MedKoo Biosciences

CAS-No: 130308-48-4

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

Laboratory chemicals, Synthesis of substances. Identified uses:

1.3 Details of the supplier of the safety data sheet

MedKoo Biosciences, Inc. Company:

2500 Gateway Centre Blvd. Suite 400, Morrisville, NC 27560, USA

Telephone: 919-636-5577 Fax: 919-980-4831

1.4 Emergency telephone number

Emergency Phone # 911 (in USA) or local emergency phone#

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with (EC) No 1272/2008 [CLP]

Skin irritation (Category 2), H315

Serious eye damage (Category 1), H318

Respiratory sensitisation (Category 1), H334

Skin sensitisation (Category 1), H317 Germ cell mutagenicity (Category 2), H341

Reproductive toxicity (Category 2), H361

Specific target organ toxicity - single exposure (Category 1), H370

Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335

Chronic aquatic toxicity (Category 4), H413

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

2.2 GHS Label elements, including precautionary statements

Pictogram:

Signal word: Danger

Hazard statement(s)

H302 Harmful if swallowed H315: Causes skin irritation.

May cause an allergic skin reaction H317: H319: Causes serious eve irritation.

May cause allergy or asthma symptoms or breathing difficulties if inhaled. H334:

May cause respiratory irritation. H335: Suspected of causing genetic defects. H341:

Suspected of damaging fertility or the unborn child. H361:

Causes damage to organs. H370:

May cause long lasting harmful effects to aquatic life. H413:

MedKoo Cat#:314226 Page 1 of 8 Precautionary statement(s)

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P260: Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.

P264: Wash skin thoroughly after handling.

P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area.

P272: Contaminated work clothing should not be allowed out of the workplace.

P273: Avoid release to the environment.

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

P301 + P312 + P330: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

Rinse mouth.

P302 + P352 + P332: IF ON SKIN: Wash with plenty of soap and water.

P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable

for breathing.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P310: Immediately call a POISON CENTER/doctor.

P321: Specific treatment (see supplemental first aid instructions on this label).

P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364: Take off contaminated clothing and wash before reuse.
P403 + P233: Store in a well-ventilated place. Keep container tightly closed.

P405: Store locked up.

P501: Dispose of contents/container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms: Firazyr

Formula: $C_{59}H_{89}N_{19}O_{13}S$ Molecular weight: 1304.52 CAS-No: 130308-48-4

Hazardous components

Component	Classification	Concentration
Icatibant	Skin Irrit. 2; Eye Dam. 1; Resp. Sens. 1; Skin Sens. 1; Muta. 2; Repr. 2; STOT	<= 100 %
	SE 3; Aquatic Chronic 4; H315, H317, H318, H334, H335, H341, H361, H413	

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

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. Move out of dangerous area.

If inhaled

Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel.

Get immediate medical attention.

In case of skin contact

Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In case of eye contact

Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel

If swallowed

Wash out mouth with water provided person is conscious. Never give anything by mouth to an

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unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

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

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

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

Use water spray to cool fire-exposed containers.

5.2 Special hazards arising from the substance or mixture

In combustion, may emit toxic fumes.

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

5.4 Further information

No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid raising and breathing dust, and provide adequate ventilation.

As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover spillage with suitable absorbent material. Using non-spark tools, sweep up material and place in an appropriate container. Decontaminate spill site with 10% caustic solution and ventilate area until after disposal is complete. Transfer to a chemical waste container for disposal in accordance with local regulations.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Use in a chemical fume hood, with air supplied by an independent system. Avoid inhalation, contact with eyes, skin and clothing. Avoid the formation of dust and aerosols. Use in a well-ventilated area. Keep away from sources of ignition. Avoid prolonged or repeated exposure.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool, well-ventilated area. Keep away from direct sunlight. Keep container tightly sealed until ready for use. Recommended storage temperature: Store at -20°C

7.3 Specific end use(s)

Use in a laboratory fume hood where possible. Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

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Components with workplace control parameters

Component	CAS-No.	Value	Control parameters	Basis
Icatibant	130308-48-4	N/A	N/A	N/A

8.2 Exposure controls

Appropriate engineering controls

Use in a fume hood where applicable. Ensure all engineering measures described under section 7 of SDS are in place. Ensure laboratory is equipped with a safety shower and eye wash station.

Personal protective equipment

Eye/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.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Data source

KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374. 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, 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 particle respirator type N100 (US) or type P3 (EN 143) 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance Form: Color: White to off-white

Form: crystalline solid powder

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d) pH No data available e) Melting point/freezing No data available

point

f) Initial boiling point and No data available

boiling range

g) Flash point
No data available
h) Evaporation rate
i) Flammability (solid, gas)
No data available
No data available
No data available
No data available

explosive limits

k) Vapour pressure
I) Vapour density
Mo data available
No data available

water

p) Auto-ignition temperature
q) Decomposition temperature
r) Viscosity
s) Explosive properties
No data available

9.2 Other safety information

No data available

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: Polymerization will not occur

10.4 Conditions to avoid: No data available

10.5 Incompatible materials: Strong acids/alkalis, strong oxidizing agents

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx)

Other decomposition products - In combustion may emit toxic fumes.

In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Inhalation:

Dermal

No data available

No data available

No data available

Skin corrosion/irritation: No data available

Serious eye damage/eye irritation: No data available

Respiratory or skin sensitisation

Germ cell mutagenicity: No data available

Hamster: No data available Lungs: No data available

Cytogenetic analysis: No data available

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Mouse: No data available

Micronucleus test: No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable,

possible or confirmed human carcinogen by IARC.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known

or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a

carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

Reproductive toxicity - Rat - No data available

Maternal Effects: No data available Effects on Newborn: No data available

Developmental Toxicity - Rat - No data available

Specific Developmental Abnormalities: No data available

Specific target organ toxicity - single exposure Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure: No data available

Aspiration hazard: No data available

Additional Information

RTECS: EK7907100

Alopecia., Liver injury may occur., Kidney injury may occur., Nausea, Headache, Vomiting, bone marrow depression

Stomach - Irregularities - No data available Central nervous system - No data available Kidney - Irregularities - No data available Heart - Irregularities - No data available

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Avoid release into the environment.

Runoff from fire control or dilution water may cause pollution.

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

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects: No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Dispose in accordance with local, state, and federal regulations.

Contaminated packaging

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14. TRANSPORT INFORMATION

DOT (US): Not dangerous goods **IMDG:** Not dangerous goods **IATA:** Not dangerous goods

Transport in accordance with local, state, and federal regulations.

15. REGULATORY INFORMATION

SARA 302 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 313.

SARA 311/312 Hazards

Acute Health Hazard, Chronic Health Hazard

Massachusetts Right To Know Components

Components	CAS-No.	Revision data
Icatibant	130308-48-4	N/A

Pennsylvania Right To Know Components

Components	CAS-No.	Revision data
Icatibant	130308-48-4	N/A

New Jersey Right To Know Components

Components	CAS-No.	Revision data
Icatibant	130308-48-4	N/A

California Prop. 65 Components

Components	CAS-No.	Revision data
Icatibant	130308-48-4	N/A

16. OTHER INFORMATION

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

Acute Tox. Acute toxicity

Aquatic Chronic Chronic aquatic toxicity
Eye Dam. Serious eye damage

Eye Irrit. Eye irritation Flam. Liq. Flammable liquids

H225 Highly flammable liquid and vapour.

H301 + H311 + H331 Toxic if swallowed, in contact with skin or if inhaled

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.
 H336 May cause drowsiness or dizziness.
 H341 Suspected of causing genetic defects.

H361 Suspected of damaging fertility or the unborn child.

H370 Causes damage to organs.

H413 May cause long lasting harmful effects to aquatic life.

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Muta. Germ cell mutagenicity
Repr. Reproductive toxicity
Resp. Sens. Respiratory sensitisation

Skin Irrit. Skin irritation
Skin Sens. Skin sensitisation

STOT SE Specific target organ toxicity - single exposure

HMIS Rating

Health hazard: 2

Chronic Health Hazard: *

Flammability: 0 Physical Hazard 0

NFPA Rating

Health hazard: 2 Fire Hazard: 0 Reactivity Hazard: 0

Further information

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Preparation Information

MedKoo Biosciences, Inc. Product Safety – multiple Region

Tel: 919-636-5577

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