

Safety Data Sheet According to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

| Date of compilation | : | February 27, 2017 |
|---------------------|---|---|
| File Name | : | 0811Gj Ghs05 Div.3 sds N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester |
| Revision Number | : | 05 |
| Date of Issue | : | February 26, 2024 |
| Revision Due Date | : | January , 2027 |
| Supersedes date | : | January 02, 2024 |
| Supersedes version | : | 0811Gj Ghs04 Div.3 sds N-[[3-amino-4-(methyl amino) phenyl] |
| | | carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester |



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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

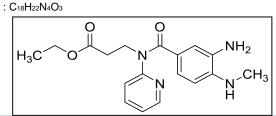
1.1. Product identifier PRODUCT NAME CAS RN EC#

SYSTEMATIC NAME

SYNONYMS

- : N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester
- : 212322-56-0
 - : 606-728-0
 - : Ethyl 3-(3-amino-4-(methylamino)-N-(pyridin-2-yl)benzamido)propanoate
 - : N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester; Ethyl N-[3-amino-4-(methylamino)benzoyl]-N-pyridin-2-yl-β-alaninate.

MOLECULAR FORMULA STRUCTURAL FORMULA



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

1.2.1. Relevant identified uses

N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester is used in the manufacture of Dabigatron.

Uses advised against: None

1.3. Details of the supplier of the safety data sheet

Jubilant Ingrevia Limited

FACTORY & REGISTERED OFFICE: Jubilant Ingrevia Limited, Bhartiagram, Gajraula, District: Amroha, Uttar Pradesh-244223, India. T +91-5924-267437, +91-5924-267438

HEAD OFFICE: Jubilant Ingrevia Limited, Plot 1-A, Sector 16-A, Institutional Area, Noida, Uttar Pradesh, 201301 - India T +91-120-4361000 - F +91-120-4234881 / 84 / 85 / 87 / 95 / 96 support@jubl.com - www.jubilantingrevia.com

1.4. Emergency telephone number

For Chemical Emergency ONLY (in the case of fire, leak, spill, exposure or accident)

Call Chemtrec: 1-800-424-9300 (US), 1-703-527-3887 (Outside U.S.)

Chemtrec (India) : 000-800-100-7141

For ALL other emergencies call Emergency Control Room Gajraula at 99970 22412

SECTION 2: HAZARD(S) IDENTIFICATION

2.1. Classification of the substance or mixture

GHS-US classification

| Skin corrosion/Irritation: Category 2 | H315 | Causes skin irritation. |
|---|------|-----------------------------------|
| Eye damage/Irritation: Category 2A | H319 | Causes serious eye irritation. |
| Specific Target Organ Toxicity SE: Category 3 | H335 | May cause respiratory irritation. |

2.2. Label Elements



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Hazard Pictogram: GHS 07

Signal Word: Warning!

HAZARD AND PRECAUTIONARY STATEMENTS:

HAZARD STATEMENTS

- H315: Causes skin irritation.
- H319: Causes serious eye irritation.
- H335: May cause respiratory irritation.

PRECAUTIONARY STATEMENTS

- P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
- P264: Wash hands, eyes and face thoroughly after handling.
- P271: Use only outdoors or in a well-ventilated area.
- P280: Wear protective gloves/clothing and eye/face protection.
- P302+P352: IF ON SKIN: Wash with plenty of soap and water.
- P304+340: IF INHALED: Removed victim to fresh air and keep at rest in a position comfortable for breathing.
- P305+P51+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P332 + +P337+P313: If skin/eye irritation occurs: Get medical advice/attention.
- P362: 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 local/regional/national/international regulations.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical | CAS # | EC# | Purity | GHS Classification |
|---|-------------|-----------|-----------|--|
| N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)- βalanine ethyl ester | 212322-56-0 | 606-728-0 | 98% by GC | Skin corrosion/Irritation: Category 2 Eye damage/Irritation: Category 2A STOT SE: Category 3 |

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Key symptoms

- Acute effects
 - N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester causes Inflammation of the eye and is characterized by redness, watering, and itching. Skin inflammation is characterized by itching, scaling, reddening, or, occasionally, blistering. It may cause irritation to mucous membrane and upper respiratory tract.

Chronic effects

• To the best of our knowledge, the chronic health effects of this product have not been fully investigated.

FIRST AID

- Eyes: Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for at least 15-20 minutes, while holding the eyelid(s) open. Remove contact lenses if easy to do so. Continue rinsing. If irritation persists, seek medical attention.
- Skin: Immediately take off all contaminated clothing. Quickly and gently blot or brush away excess chemical. Wash thoroughly with lukewarm, gently flowing water and non-abrasive soap for 15-20 minutes. Wash contaminated clothes before reuse. If irritation persists, obtain medical advice.
- Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Give artificial respiration if victim is not breathing. Administer oxygen if breathing is difficult.





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- Ingestion: If swallowed call a poison center if you feel unwell. Rinse mouth. DO NOT induce vomiting by use of emetics. Seek medical attention.
- Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing media

Appropriate extinguishing media: Dry chemical powder, carbon dioxide, and alcohol resistant foam. Water may also be used. Water can be
effective in cooling down the fire-exposed containers and knocking down the vapors. Water jets may be used to flush spills away and dilute the
same to non-flammable mixtures fog or alcohol-resistant foam by directing streams to the periphery of the fires to prevent spread.

Special Protective Equipment and Precautions for Fire Fighter:

- Evacuate the area and fight fires from a safe distance.
- If tank, rail car or tank truck is involved in a fire, ISOLATE for 800 meters (1/2 mile) in all directions; also, consider initial evacuation for 800
 meters (1/2 mile) in all directions or as per locally valid procedures.
- · Fire fighters must wear Self Contained Breathing Apparatus (SCBA) and full protective clothing. The chemical is harmful in contact with skin.
- Report any run-off of fire waters contaminated with this chemical as per local and federal procedures applicable.

Advice for firefighters:

- Wear self-contained breathing apparatus.
- Wear protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- Avoid breathing vapors and contact with skin and eyes.
- Shut off leak source if possible.
- Shut off all possible sources of ignition.
- Wipe up.
- Decontaminate all equipment.
- Alert Emergency Responders and tell them location and nature of hazard.
- Shut off all possible sources of ignition and increase ventilation.
- Wear protective clothing, full boots, impervious gloves, safety glasses and Self Contained Breathing Apparatus (SCBA), as may be deemed appropriate.
- Clear area of personnel and move upwind.
- Stop leaks if possible.
- Prevent, by any means available, spillage from entering drains or water and watercourses.
- Collect recoverable product into labeled containers for recycling, recovery or disposal.
- Contain spill with sand, earth or vermiculite.
- Spread area with lime or absorbent material, and leave for at least 1 hour before washing.
- Clean up all tools and equipment.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

- Wear protective gloves/clothing and eye/face protection.
- Wash thoroughly after handling.
- · Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- · Launder contaminated clothing before re-use.
- If on skin or hair, IMMEDIATELY remove all contaminated clothing and rinse/shower with plenty of water.
- Use in a well-ventilated place/Use protective clothing commensurate with exposure levels.

Storage

- Store at ambient temperature, in a well-ventilated place.
- · Store away from incompatible materials.
- · Keep container tightly closed.
- Keep securely closed when not in use.
- Keep in original containers.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION



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Control parameters

Exposure Limits Values

| Chemical name | STEL (ppm) | NIOSH | ACGIH | OSHA |
|--|----------------|----------------|----------------|----------------|
| N-[[3-amino-4-(methyl amino) phenyl] carbonyl]N- (pyridin-2-yl)-β-alanine ethyl ester | None available | None available | None available | None available |

• Exposure Limits (International): Not available.

Exposure controls

Appropriate Engineering Controls:

Provide exhaust ventilation or other engineering controls to keep the relevant airborne concentrations below their respective occupational
exposure limits. Local ventilation is usually preferred. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protection

- Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.
- Hands: Wear appropriate protective gloves to prevent skin exposure.

Eyes: Safety goggles/ Chemical Safety glasses and Face shield.

- Clothing: Boots and clothing to prevent contact.
- Respirator: Dust production: dust mask with filter
- For emergency situations, wear a positive pressure, pressure-demand, full face piece self- contained breathing apparatus (SCBA) or pressuredemand supplied air respirator with escape SCBA and a fully-encapsulating, chemical resistant suit. (EPA, 1998).

General Hygiene and general comments:

- Wash hands and face after working with substance.
- · Immediately change contaminated clothing.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties.

| Sr.No. | Parameter | Typical value |
|--------|--------------------------------|------------------------------------|
| 1) | Appearance | White to brown colored solid |
| 2) | Molecular weight | 342.39 g/mol |
| 3) | Odor | Characteristic Odor |
| 4) | Odor Threshold | Not available |
| 5) | рН | ~ 6.0 |
| 6) | Melting point | 103–105 °C |
| 7) | Boiling point | 576.2°C at 760 mmHg |
| 8) | Flash point | 221.8±28.7 °C |
| 9) | Evaporation rate (n-BuAc=1) | Not available |
| 10) | Explosive limits | Not available |
| 11) | Log Pow | 1.37 |
| 12) | Vapor pressure | 2.17E-010 mmHg at 25°C (Estimated) |
| 13) | Relative Vapor density (air=1) | Not available |
| 14) | Relative density | 1.3 ± 0.1 g/cm ³ |
| 15) | Specific gravity | 302 g/mL |



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| 16) | Solubility | Slightly soluble in water. Soluble in Methanol, dichloromethane, Acetone |
|-----|---------------------------|--|
| 17) | рКа (@25 °C) | 5.37 ± 0.11 |
| 18) | Auto-ignition temperature | Not available |
| 19) | Decomposition temperature | Not available |
| 20) | Viscosity | Not applicable |
| 21) | Flammable material | Not flammable |

SECTION 10: STABILITY AND REACTIVITY

- Reactivity: No data available
- Stability: Stable under normal conditions of temperature and pressure.
- Conditions to avoid: Not available.
- Incompatible chemicals: Strong oxidizing agents.
- Hazardous decomposition: Hazardous decomposition may produce carbon monoxide, carbon dioxide, nitrogen oxides.
- Hazardous Polymerization: Not reported.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester causes Inflammation of the eye and is characterized by redness, watering, and itching. Skin inflammation is characterized by itching, scaling, reddening, or, occasionally, blistering. It may cause irritation to mucous membrane and upper respiratory tract.

RTECS#: Not Available

Toxicity data: LD50 (Oral) Rat: >5000mg/kg bw

| Skin corrosion/irritation | : | Causes skin irritation. |
|-----------------------------------|---|---|
| Serious eye damage/irritation | : | Causes serious eye irritation. |
| Respiratory or skin sensitization | : | No data available |
| Germ cell Mutagenicity | : | No data available |
| Carcinogenicity | : | Not listed by NTP, IARC and OSHA. Not present on the EU CMR list. According to information presently available N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester is not found to be carcinogenic. |
| Reproductive toxicity | : | No data available. |
| STOT-single exposure | : | May cause irritation to respiratory system |
| STOT- repeated exposure | : | No data available. |
| Aspiration Hazards | : | No data available. |
| | | |

SECTION 12:

ECOLOGICAL INFORMATION

12.1. Toxicity



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12.1.1 Eco toxicity:

No data available

12.2. Persistence and degradability

· Not readily biodegradable.

12.3. Bioaccumulative potential

N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester (212322-56-0)

| Bio concentration factor | 7.821 |
|--------------------------|-------|
| Log Kow | 1.86 |

Based on the Log Kow and Bio concentration factor value it is expected to have low potential to concentrate in fatty tissue of fish and aquatic organisms. These results are estimated and it is recommended that this material should not be disposed into the environment.

12.4. Mobility in soil

N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester (212322-56-0)

| Log Koc | 1.749. Moderate absorption in soil |
|----------------------|---|
| Henry's Law constant | 3.77X10 ⁻²⁰ atm-m ³ /mole (estimated) |
| Log Kow | 1.86. Low potential to bio accumulate. |

N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester may have the potential to leach through soil and enter groundwater.

Other adverse effects.

Environment Fate:

No additional information available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

- Burn in a chemical incinerator equipped with an afterburner and scrubber.
- Dispose of this material in accordance with standard practice for disposal of potentially hazardous materials as required by applicable federal, state or local laws. Note that disposal regulations may also apply to empty containers and equipment rinsates.

SECTION 14: TRANSPORT INFORMATION

This substance is considered to be non-hazardous for transportation by Air/ Rail/ Road and Sea and thus not regulated by IATA/ ICAO/ ARD/ RID/ IMO/ IMDG/ US DOT.

| Transport | Agency | Class | UN Number |
|--------------------|-------------|--------------------|----------------|
| Land Transport | ADR/RID/DOT | Not Dangerous good | Not Applicable |
| Maritime Transport | IMDG | Not Dangerous good | Not Applicable |
| Air Transport | ΙΑΤΑ | Not Dangerous good | Not Applicable |

SECTION 15: REGULATORY INFORMATION

European Union Information

Classification as per CLP Regulation 1272/2008:

Hazards Class and Category: Skin Irrit Cat. 2; Eye Irrit. Cat. 2; STOT SE Cat. 3.

Hazard Statements: H315; H319; H335.



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| Chemical Inventory Lists: | Status |
|---------------------------|------------|
| TSCA: | Not listed |
| EC Inventory | Listed |
| Canada(DSL/NDSL): | Not listed |
| Japan: | Not listed |
| Korea: | Not listed |
| Australia: | Not listed |
| Taiwan | Not listed |
| The Philippines | Not listed |
| China | Not listed |

US information

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester is not listed SARA 302/304 : N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester is not listed SARA 311/312 : See section 2 for more information California Prop. 65: N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester is not listed

CAA (Clean Air Act): 3 N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester is not listed CWA (Clean Water Act): N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester is not listed CWA (Clean Water Act): N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester is not listed

EU Information

Water hazard class (WGK): WGK 3 (Severely hazardous to water)

Substance of Very High Concern (SVHC) according to the REACH Regulations (EC) No. 1907/2006: N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester is not listed

SECTION 16: OTHER INFORMATION

|) Compilation information of s | Compilation information of safety data sheet | | |
|--------------------------------|--|--|--|
| Date of compilation | : February 27, 2017 | | |
| Chemical | : N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester | | |
| CAS # | : 212322-56-0 | | |
| File Name | : 0811Gj Ghs05 Div.3 sds N-[[3-amino-4-(methyl amino) phenyl] carbonyl]-N-(pyridin-2-yl)-β-alanine ethyl ester | | |
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| | | | |

b) A key or legend to aberrations and acronyms used in the safety data sheet

- PBT =Persistent Bio accumulative and Toxic.
- vPvB= Very Persistent and Very Bio accumulative.
- SCBA= Self Contained Breathing Apparatus.
- NIOSH REL= National Institute for Occupational Safety and Health Recommended Exposure Limit.
- OSHA PEL=Occupational Safety and Health Administration Permissible Exposure Limit.
- OELTWA= Occupational Exposure Limit Time Weighted Averages.
- RTECS= Registry of Toxic Effects of Chemical Substances.
- NTP=National Toxicology Program.
- IARC= International Agency for Research on Cancer.
- EPA=Environmental Protection Agency.
- TSCA= Toxic Substances Control Act.
- SARA= Superfund Amendments and Reauthorization Act.
- WHIMS= Workplace Hazardous Materials Information System.



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- DSL/NDSL= Domestic/Non-Domestic Substances List.
- BCF = Bio Concentration Factor.
- TLV = Threshold Limit Value.
- ACGIH = American Conference of Governmental Industrial Hygienists.
- REACH = Registration, Evaluation .Authorization and Restriction of Chemicals.
- CLP = Classification, Labeling and Packaging.
- LD / LC = Lethal Doses / Lethal Concentration.
- GHS = Globally Harmonized System.
- ADR = Accord European relative au transport international de merchandises.
- IMDG-Code = International Maritime Code for Dangerous Goods.
- EmS = Emergency measures on Sea.
- ICAO = International Civil Aviation Organization.
- IATA/DGR= International Air Transport Association/Dangerous Goods Regulation.

c) Key Literature reference and sources for data

Biographical reference and data sources

- Globally Harmonized System of Classification and Labelling of Chemicals.
- CLP REG (regulation) (EC) no. 1272/2008, last modification by regulation (EC) no. 790/2009.

SDS US (GHS HazCom 2012)

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.

(End of Safety Data Sheet)