

SAFETY DATA SHEETS

According to the UN GHS revision 10

Version: 1.1
Creation Date: July 15, 2024
Revision Date: March 22, 2025

SECTION 1: Identification

1.1 GHS Product identifier

Product name Apixaban Impurity 111

1.2 Other means of identification

Product number C4X-1088111

Other names 4-Methoxyaniline; 4-methoxyaniline; Benzenamine, 4-methoxy-

1.3 Recommended use of the chemical and restrictions on use

Identified uses For laboratory and Industrial use only.

Uses advised against no data available

1.4 Supplier's details

Company CATO Research Chemicals Inc.

Address 3/F,Building B,No.179 BASIGO, Guangpu Rd East,Huangpu Dist,Guangzhou

Telephone +86-20-81960175

1.5 Emergency phone number

Emergency phone number +86-20-81960175

Service hours 'Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

Acute toxicity - Category 2, Oral

Acute toxicity - Category 1, Dermal

Acute toxicity - Category 2, Inhalation

Specific target organ toxicity – repeated exposure, Category 2

Hazardous to the aquatic environment, short-term (Acute) - Category Acute 1

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word

Danger

Hazard statement(s)

H300 Fatal if swallowed

H310 Fatal in contact with skin

H330 Fatal if inhaled

H373 May cause damage to organs through prolonged or repeated exposure

H400 Very toxic to aquatic life

Precautionary statement(s)

Prevention

P264 Wash ... thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P262 Do not get in eyes, on skin, or on clothing.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P271 Use only outdoors or in a well-ventilated area.

P284 [In case of inadequate ventilation] wear respiratory protection.

P273 Avoid release to the environment.

Response	P301+P316 IF SWALLOWED: Get emergency medical help immediately. P321 Specific treatment (see ... on this label). P330 Rinse mouth. P302+P352 IF ON SKIN: Wash with plenty of water/... P316 Get emergency medical help immediately. P361+P364 Take off immediately all contaminated clothing and wash it before reuse. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P320 Specific treatment is urgent (see ... on this label). P319 Get medical help if you feel unwell. P391 Collect spillage.
Storage	P405 Store locked up. P403+P233 Store in a well-ventilated place. Keep container tightly closed.
Disposal	P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

2.3 Other hazards which do not result in classification

no data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Apixaban Impurity 111	p-anisidine	104-94-9	203-254-2	≈ 99%

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

If inhaled

Fresh air, rest. Refer for medical attention.

Following skin contact

Remove contaminated clothes. Rinse and then wash skin with water and soap.

Following eye contact

Rinse with plenty of water (remove contact lenses if easily possible).

Following ingestion

Rinse mouth. Give one or two glasses of water to drink. Refer for medical attention .

4.2 Most important symptoms/effects, acute and delayed

Exposure Routes: inhalation, skin absorption, ingestion, skin and/or eye contact Symptoms: Headache, dizziness; cyanosis; red blood cell Heinz bodies Target Organs: Blood, kidneys, liver, cardiovascular system, central nervous system (NIOSH, 2016)

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Immediate first aid: Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand-valve resuscitator, bag-valve-mask device, or pocket mask, as trained. Perform CPR as necessary. Immediately flush contaminated eyes with gently flowing water. Do not induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature. Obtain medical attention. Aniline and related compounds

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Use dry chemical, carbon dioxide, or alcohol foam extinguishers. Vapors are heavier than air and will collect in low areas. Vapors may travel long distances to ignition sources and flashback. Vapors in confined areas may explode when exposed to fire. Storage containers and parts of containers may rocket great distances, in many directions. If material or contaminated runoff enters waterways, notify downstream users of potentially contaminated waters. Notify local health and fire officials and pollution control agencies. From a secure, explosion-proof location, use water spray to cool exposed containers. If cooling streams are ineffective (venting sound increases in volume and pitch, tank discolours or shows any signs of deforming), withdraw immediately to a secure position ... The only respirators recommended for fire fighting are self-contained breathing apparatuses that have full facepieces and are operated in a pressure-demand or other positive-pressure mode. Anisidines

5.2 Specific hazards arising from the chemical

This chemical is flammable. (NTP, 1992)

5.3 Special protective actions for fire-fighters

Use water spray, foam, powder, carbon dioxide.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal protection: filter respirator for organic gases and particulates adapted to the airborne concentration of the substance. Do NOT let this chemical enter the environment. Sweep spilled substance into covered containers. If appropriate, moisten first to prevent dusting. Then store and dispose of according to local regulations.

6.2 Environmental precautions

Personal protection: filter respirator for organic gases and particulates adapted to the airborne concentration of the substance. Do NOT let this chemical enter the environment. Sweep spilled substance into covered containers. If appropriate, moisten first to prevent dusting. Then store and dispose of according to local regulations.

6.3 Methods and materials for containment and cleaning up

Spill handling: Evacuate persons not wearing protective equipment from area of spill or leak until clean-up is complete. Remove all ignition sources. Collect powdered material in the most convenient and safe manner and deposit in sealed containers. Ventilate area after clean-up is complete. If material or contaminated runoff enters waterways, notify downstream users of potentially contaminated waters. It may be necessary to contain and dispose of this chemical as a hazardous waste. Contact your Department of Environmental Protection or your regional office of the federal EPA for specific recommendations. Anisidines

SECTION 7: Handling and storage

7.1 Precautions for safe handling

NO open flames. Prevent deposition of dust. Closed system, dust explosion-proof electrical equipment and lighting. Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

7.2 Conditions for safe storage, including any incompatibilities

Separated from strong oxidants, strong bases, acids, chloroformates and food and feedstuffs. Provision to contain effluent from fire extinguishing. Store in an area without drain or sewer access. Store in tightly closed containers in a cool, dark, well-ventilated area. Protect against sunlight and strong oxidizers. Metal containers involving the transfer of this chemical should be grounded and bonded. Where possible, automatically pump liquid from drums or other storage containers to process containers. Drums must be equipped with self-closing valves, pressure vacuum bungs, and flame arresters. Use only non-sparking tools and equipment, especially when opening and closing containers of this chemical. Sources of ignition, such as smoking and open flames, are prohibited where this chemical is used, handled, or stored in a manner that could create a potential fire or explosion hazard. A regulated, marked area should be established where this chemical is handled, used, or stored ... Anisidines

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

TLV: 0.5 mg/m³, as TWA; (skin); A4 (not classifiable as a human carcinogen); BEI issued. MAK: skin absorption (H); carcinogen category: 3B

Biological limit values

no data available

8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear face shield or eye protection in combination with breathing protection.

Skin protection

Protective gloves. Protective clothing.

Respiratory protection

Use ventilation, local exhaust or breathing protection.

Thermal hazards

no data available

SECTION 9: Physical and chemical properties and safety characteristics

Physical state	Solid. Powder.
Colour	Light yellow brown.
Odour	Amine-like odour
Melting point/freezing point	>= 49.33 - < 55 °C. Atm. press.:975.66 hPa.
Boiling point or initial boiling point and boiling range	243 °C. Remarks:Other details not available.
Flammability	Combustible Solid

Lower and upper explosion limit/flammability limit	no data available
Flash point	118.6 °C. Atm. press.:975.8 hPa.
Auto-ignition temperature	515 °C. Remarks:Other details not available.
Decomposition temperature	no data available
pH	8.34. Remarks:Basic.
Kinematic viscosity	no data available
Solubility	Partially miscible with water
Partition coefficient n-octanol/water	log Pow = 0.95. Remarks:Other details not available.
Vapour pressure	3.99 Pa. Temperature:20 °C. Remarks:0.03 mmHg.
Density and/or relative density	1.18 g/cm ³ . Temperature:20 °C.
Relative vapour density	4.25 (NTP, 1992) (Relative to Air)
Particle characteristics	no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Decomposes on burning. This produces toxic fumes including nitrogen oxides. The solution in water is a weak base. Reacts with acids, chloroformates and strong oxidants. Attacks some coatings, some forms of plastic and rubber.

10.2 Chemical stability

no data available

10.3 Possibility of hazardous reactions

Combustible.As a result of flow, agitation, etc., electrostatic charges can be generated. Dust explosion possible if in powder or granular form, mixed with air.P-ANISIDINE may be sensitive to heat, light and moisture. Reacts with acids, acid chlorides, acid anhydrides, chloroformates and strong oxidizing agents. Incompatible with alkaline materials. Incompatible with aldehydes, ketones and nitrates. (NTP, 1992)

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Incompatible with strong oxidizers, with risk of fire or explosions. Attacks some coatings and some forms of plastic and rubber. Anisidines

10.6 Hazardous decomposition products

When heated to decomposition it emits toxic fumes of nitrogen oxides.

SECTION 11: Toxicological information

Acute toxicity

- Oral: LD50 Rat oral 1400 mg/kg
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

No data are available in humans. Inadequate evidence of carcinogenicity in animals. OVERALL EVALUATION: Group 3: The agent is not classifiable as to its carcinogenicity to humans.

Reproductive toxicity

no data available

STOT-single exposure

The aerosol is irritating to the eyes and respiratory tract. The substance may cause effects on the blood. This may result in the formation of methaemoglobin. Medical observation is indicated. See Notes.

STOT-repeated exposure

The substance may have effects on the blood. This may result in the formation of methaemoglobin and anaemia.

Aspiration hazard

A harmful contamination of the air will be reached rather slowly on evaporation of this substance at 20°C; on spraying or dispersing, however, much faster.

SECTION 12: Ecological information

12.1 Toxicity

- Toxicity to fish: LC50 - *Oryzias latipes* - > 100 mg/L - 96 h.
- Toxicity to daphnia and other aquatic invertebrates: EC50 - *Daphnia magna* - 4.12 mg/L - 48 h. Remarks: Immobilization.
- Toxicity to algae: EC50 - *Chlorella vulgaris* - 0.937 mg/L - 72 h.
- Toxicity to microorganisms: MIC - *E. coli* ATCC 11775 and *Mycobacterium smegmatis* M169 - 357.1 mg/L - 48 h.

12.2 Persistence and degradability

AEROBIC: p-Anisidine, present at 100 mg/L, reached 65.3% of its theoretical BOD in 2 weeks using an activated sludge inoculum at 30 mg/L in the Japanese MITI test(1). p-Anisidine degraded 82% in river water obtained from Mino River, Japan, and 2% in seawater obtained from Akashi Beach, Japan during a Cultivation Method screening test(2). p-Anisidine did not degrade during a Modified OECD test, but degraded completely after 28 days using the same procedure with a modified activated sludge (1.5 mL/L) inoculum and a test sample concn of 60 mg/L(3). Half-lives of <3 weeks in non-adapted inoculum and <2 weeks in adapted inoculum were obtained during an adapted, semistatic OECD biodegradability test and dynamic Pitter test(4). p-Anisidine, present at 25 µg/L and inoculated with a mixed culture of soil microorganisms in an aqueous mineral salts medium, underwent complete degradation in 64 days as indicated by a total loss of UV absorbency(5). Partially purified enzymes of the soil fungus *Geotrichum candidum* transformed the anisidines into colored polyaromatic hydrocarbons(6). Pure cultures of the bacterium *Escherichia coli* metabolized p-anisidine in the presence of nitrate, as indicated by a color change occurring within 24 hours of incubation; a disappearance rate of 0.10/hr was reported(7).

12.3 Bioaccumulative potential

An estimated BCF of 3.2 was calculated for p-anisidine(SRC), using a log Kow of 0.95(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

12.4 Mobility in soil

The Koc of p-anisidine is estimated as 45(SRC), using a log Kow of 0.95(1) and a regression-derived equation(2). According to a classification scheme(3), this estimated Koc value suggests that p-anisidine is expected to have very high mobility in soil. The pKa of p-anisidine is 5.36(4), indicating that this compound will partially exist in the cation form in the environment and cations generally adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts(5).

12.5 Other adverse effects

no data available

SECTION 13: Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

SECTION 14: Transport information

14.1 UN Number

ADR/RID: UN2811 (For reference only, please check.) IMDG: UN2811 (For reference only, please check.) IATA: UN2811 (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: TOXIC SOLID, ORGANIC, N.O.S. (For reference only, please check.) IMDG: TOXIC SOLID, ORGANIC, N.O.S. (For reference only, please check.) IATA: TOXIC SOLID, ORGANIC, N.O.S. (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: 6.1 (For reference only, please check.) IMDG: 6.1 (For reference only, please check.) IATA: 6.1 (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: I (For reference only, please check.) IMDG: I (For reference only, please check.) IATA: I (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: Yes

IMDG: Yes

IATA: Yes

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
p-anisidine	p-anisidine	104-94-9	203-254-2
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Listed.
China Catalog of Hazardous chemicals 2015			Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Listed.
Vietnam National Chemical Inventory			Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Listed.
Korea Existing Chemicals List (KECL)			Listed.

SECTION 16: Other information

Information on revision

Creation Date July 15, 2024
Revision Date March 22, 2025

Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Other Information

Depending on the degree of exposure, periodic medical examination is suggested. Specific treatment is necessary in case of poisoning with this substance; the appropriate means with instructions must be available. See ICSC 0970.

Any questions regarding this SDS, Please send your inquiry to info@cato-chem.com

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