SAFETY DATA SHEET

1. Identification

Product identifier **N-Nitroso Dabigatran Etexilate Solution**

Other means of identification

Catalog number 1A04040

Chemical name ethyl 3-(2-(((4-(N-((hexyloxy)carbonyl)carbamimidoyl)phenyl)(nitroso)amino)methyl)-1-methyl-N-(pyridin-2-yl)-1H-benzo[d]imidazole-5-carboxamido)propanoate

Recommended use For analytical laboratory use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
United States

Telephone Customer Service 301-881-0666

Website www.usp.org

E-mail AMTech@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards	Flammable liquids	Category 2
Health hazards	Acute toxicity, oral	Category 4
	Acute toxicity, dermal	Category 4
	Acute toxicity, inhalation	Category 4
	Serious eye damage/eye irritation	Category 2A
	Carcinogenicity	Category 2

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement Highly flammable liquid and vapor. Harmful if swallowed. Harmful in contact with skin. Causes serious eye irritation. Harmful if inhaled. Suspected of causing cancer.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use explosion-proof electrical/ventilating/lighting equipment. Keep container tightly closed. Use only non-sparking tools. Take precautionary measures against static discharge. Avoid breathing vapors. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Use only outdoors or in a well-ventilated area.

Response	If exposed or concerned: Get medical advice/attention. If swallowed: Rinse mouth. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of fire: Use appropriate media to extinguish.
Storage	Store in a well-ventilated place. Keep cool. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Pharmaceutical related compound of unknown potency.

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Acetonitrile	Methyl cyanide Cyanomethane Ethyl nitrile	75-05-8	99.9
N-Nitroso Dabigatran Etexilate		2892260-29-4	0.1

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation	Remove person to fresh air and keep at rest in a position comfortable for breathing. Do not use mouth-to-mouth method if the substance is inhaled. Oxygen or artificial respiration if needed. Call a poison center or doctor/physician if you feel unwell.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms/effects, acute and delayed	Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects. Gastrointestinal disturbances. Cardiovascular effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Patients with significant exposure to acetonitrile should be treated as for cyanide poisoning. Treatment may include the following: Vomiting usually occurs spontaneously. Do not induce vomiting. Perform gastric lavage to decontaminate or administer activated charcoal. Admit patients with potential ingestion or inhalation exposure to a hospital for at least 24 to 48 hours of observation for the development of cyanide poisoning. Toxicity may be prolonged, with clinical deterioration following initial response to antidote treatment reported for as long as 3 days following ingestion. Monitor arterial blood gasses, pulse oximetry, cardiac function, and plasma lactate levels. Correct severe metabolic acidosis with sodium bicarbonate. Correct fluid and electrolyte disturbances. Administer a cyanide antidote kit containing hydroxocobalamin or amyl nitrate, sodium nitrite, and sodium thiosulfate to patients who are significantly symptomatic with unstable vital signs, metabolic acidosis, impaired consciousness, seizures, coma, or cardiorespiratory compromise.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical	By heating and fire, harmful vapors/gases may be formed.
Special protective equipment and precautions for firefighters	Use protective equipment appropriate for surrounding materials.
Fire fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to cool unopened containers. In case of fire and/or explosion do not breathe fumes.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Highly flammable liquid and vapor.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Wear appropriate personal protective equipment. Avoid inhalation of vapors. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Absorb spillage with suitable absorbent material. Remove sources of ignition. Keep combustibles (wood, paper, oil, etc.) away from spilled material. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Acetonitrile (CAS 75-05-8)	PEL	70 mg/m3
		40 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Acetonitrile (CAS 75-05-8)	TWA	20 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Acetonitrile (CAS 75-05-8)	TWA	34 mg/m3
		20 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

US - California OELs: Skin designation

Acetonitrile (CAS 75-05-8) Can be absorbed through the skin.

US - Minnesota Haz Subs: Skin designation applies

Acetonitrile (CAS 75-05-8) Skin designation applies.

US ACGIH Threshold Limit Values: Skin designation

Acetonitrile (CAS 75-05-8) Danger of cutaneous absorption

Appropriate engineering controls No open handling. For laboratory operation, use an engineered local exhaust ventilation (LEV) and/or enclosure or isolator system for procedures where aerosolization of solutions may occur (e.g., vortexing, pipetting, pumping). Control the potential for spills and leaks by securing all connections. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Liquid.
Form	Liquid.
Color	Colorless.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the decomposition temperature. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.

Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. Hydrogen cyanide (hydrocyanic acid).

11. Toxicological information

Information on likely routes of exposure

Inhalation Harmful if inhaled.

Skin contact Harmful in contact with skin.

Eye contact Causes serious eye irritation.

Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics Edema. Nausea. Vomiting. Diarrhea. Loss of appetite. Headache. Dizziness. Drowsiness. Stupor. Incoordination. Excitement. Depression. Impaired judgment. Weakness. Flushing. Yellow eyes and/or skin. Cough. Difficulty breathing. Blue or pale lips, fingernails, and skin. Chest pain. Irregular heartbeat. Convulsions.

Information on toxicological effects

Acute toxicity Harmful if inhaled. Harmful in contact with skin. Harmful if swallowed.

Components	Species	Test Results
Acetonitrile (CAS 75-05-8)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg, 24 Hours
Inhalation		
LC50	Rat	7500 ppm, 8 Hours
Oral		
LD50	Mouse	617 mg/kg
	Rat	1.73 g/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation Causes serious eye irritation.

Local effects

Acetonitrile

Eye irritation
Result: Irritant.
Species: Rabbit
Test Duration: 24 Hours
Severity: Moderate
Skin irritation
Result: Irritant.
Species: Rabbit
Severity: Mild.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete.

Acetonitrile

Buehler test
Result: Negative
Species: Guinea pig

Germ cell mutagenicity Knowledge about health hazard is incomplete.

Mutagenicity

Acetonitrile

Ames test
Result: Negative.
Mutagenicity: mutation at the HGPRT gene locus in Chinese hamster ovary cells
Result: Negative.

Carcinogenicity Suspected of causing cancer. No specific information regarding the carcinogenic potential of this material has been found. Nitrosamines as a class are considered to be carcinogens based on results of animal studies.

Acetonitrile

200 ppm Inhalation study
Result: No adverse effects observed.
Species: Mouse

Carcinogenicity

Acetonitrile — 400 ppm Inhalation study
Result: Equivocal evidence in males, no evidence of carcinogenicity in females
Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity — Knowledge about health hazard is incomplete.

Reproductivity

Acetonitrile — 100 - 400 mg/kg/day Reproductivity / developmental
Result: Maternal toxicity and skeletal malformations
Species: Hamster
125 - 275 mg/kg/day Reproductivity / developmental
Result: Maternal toxicity and embryo toxicity at high dose; no teratogenicity observed
Species: Rat

Specific target organ toxicity - single exposure — Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure — Knowledge about health hazard is incomplete.

Aspiration hazard — Knowledge about health hazard is incomplete.

Further information — Pharmaceutical related compound of unknown potency It is not known if occupational exposure may cause physiological effects..

12. Ecological information

Ecotoxicity

Components		Species	Test Results
Acetonitrile (CAS 75-05-8)			
Aquatic			
Crustacea	LC50	Water flea (Daphnia magna)	3600 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	> 100 mg/l, 96 hours

Persistence and degradability — No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

Acetonitrile — -0.34

Mobility in soil — No data available.

Other adverse effects — The product contains volatile organic compounds which have a photochemical ozone creation potential.

13. Disposal considerations

Disposal instructions — Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations — Dispose in accordance with all applicable regulations.

Hazardous waste code — D001: Waste Flammable material with a flash point <140 F
The waste code should be assigned in discussion between the user, the producer and the waste disposal company. U003: Waste Acetonitrile

Waste from residues / unused products — Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging — Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN1648
UN proper shipping name	Acetonitrile, solution (Acetonitrile RQ = 5005 LBS)
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	II
Packaging exceptions	150
Packaging non bulk	202
Packaging bulk	242

IATA

UN number	UN1648
UN proper shipping name	Acetonitrile solution (Acetonitrile)
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	II
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

DOT

IATA

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Acetonitrile (CAS 75-05-8) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories
Flammable (gases, aerosols, liquids, or solids)
Acute toxicity (any route of exposure)
Serious eye damage or eye irritation
Carcinogenicity

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
Acetonitrile	75-05-8	99.9

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Acetonitrile (CAS 75-05-8)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Acetonitrile (CAS 75-05-8)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 11-01-2023

Version # 01

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