

FORANE® 427A**1. PRODUCT AND COMPANY IDENTIFICATION****Company**

Arkema Inc.
900 First Avenue
King of Prussia, Pennsylvania 19406

Fluorochemicals

Customer Service Telephone Number: (800) 245-5858
(Monday through Friday, 8:00 AM to 5:00 PM EST)

Emergency Information

Transportation: CHEMTREC: (800) 424-9300
(24 hrs., 7 days a week)
Medical: Rocky Mountain Poison Center: (866) 767-5089
(24 hrs., 7 days a week)

Product Information

Product name: FORANE® 427A
Synonyms: R427A
Molecular formula: Complex Mixture
Chemical family: Hydrofluorocarbon
Product use: Refrigerant

2. HAZARDS IDENTIFICATION**Emergency Overview**

Color: Clear - colourless
Physical state: gaseous
Form: Liquefied gas
Odor: Ether-like (slightly)

***Classification of the substance or mixture:**
Gases under pressure, Liquefied gas, H280

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

GHS-Labeling

Hazard pictograms:



FORANE® 427A

Signal word: **Warning**

Hazard statements:

H280 : Contains gas under pressure; may explode if heated.

Supplemental Hazard Statements:

Overheating or overpressurizing may cause gas release or violent cylinder bursting. May decompose on contact with flames or extremely hot metal surfaces to produce toxic and corrosive products. May cause frostbite. May cause headache, nausea, dizziness, drowsiness, loss of consciousness. May cause cardiac sensitization/cardiac arrhythmia. May displace oxygen and cause rapid suffocation.

Precautionary statements:

Storage:

P403 : Store in a well-ventilated place.
P410 : Protect from sunlight.

Supplemental information:

Potential Health Effects:

Liquid : Rapid evaporation of the liquid may cause frostbite. Vapor: Vapor is heavier than air and can cause suffocation by reducing oxygen available for breathing. If inhaled: Central nervous system effects: headache, nausea, dizziness, drowsiness, loss of consciousness. Stress induced heart effects: Inhalation may cause an increase in the sensitivity of the heart to adrenaline, which could result in irregular or rapid heartbeats and reduced heart function.

Medical conditions aggravated by overexposure:

Heart disease or compromised heart function.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Ethane, 1,1,1,2-tetrafluoro-	811-97-2	50 %	H280
Ethane, pentafluoro-	354-33-6	25 %	H280
Methane, difluoro-	75-10-5	15 %	H220, H280

FORANE® 427A

Ethane, 1,1,1-trifluoro-	420-46-2	10 %	H220, H280
--------------------------	----------	------	------------

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

4. FIRST AID MEASURES

Inhalation:

If inhaled, remove victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Skin:

If on skin, flush exposed skin with lukewarm water (not hot), or use other means to warm skin slowly. Get medical attention if frostbitten by liquid or if irritation occurs. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:

Immediately flush eye(s) with plenty of water.

Ingestion:

Ingestion is not applicable - product is a gas at ambient temperatures.

Notes to physician:

Do not give drugs from adrenaline-ephedrine group.

5. FIREFIGHTING MEASURES

Extinguishing media (suitable):

Use extinguishing media appropriate to surrounding fire conditions.

Protective equipment:

Fire fighters and others who may be exposed to products of combustion should wear full fire fighting turn out gear (full Bunker Gear) and self-contained breathing apparatus (pressure demand / NIOSH approved or equivalent).

Further firefighting advice:

Fight fire with large amounts of water from a safe distance.

Stop the flow of gas if possible.

Water mist should be used to reduce vapor concentrations in air.

Cool closed containers exposed to fire with water spray.

Closed containers of this material may explode when subjected to heat from surrounding fire.

After a fire, wait until the material has cooled to room temperature before initiating clean-up activities.

Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:

FORANE® 427A

May decompose on contact with flames or extremely hot metal surfaces to produce toxic and corrosive products. Liquid and gas under pressure, overheating or overpressurizing may cause gas release and/or violent cylinder bursting.

Container may explode if heated due to resulting pressure rise.

Some mixtures of HCFCs and/or HFCs, and air or oxygen may be combustible if pressurized and exposed to extreme heat or flame.

When burned, the following hazardous products of combustion can occur:

hydrofluoric acid

Carbon oxides

Carbonyl halides

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, Emergency procedures, Methods and materials for containment/clean-up:**

Prevent further leakage or spillage if you can do so without risk. Evacuate area of all unnecessary personnel. Eliminate all ignition sources. Use Halogen leak detector or other suitable means to locate leaks or check atmosphere. Keep upwind. Evacuate enclosed spaces and disperse gas with floor-level forced-air ventilation. Avoid breathing leaked material. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits.

Protective equipment:

Appropriate personal protective equipment is set forth in Section 8.

7. HANDLING AND STORAGE**Handling****General information on handling:**

Avoid breathing gas.

Avoid contact with skin, eyes and clothing.

Keep away from heat, sparks and flames.

Wear cold-insulating gloves/face shield/eye protection.

Keep container closed.

Use only with adequate ventilation.

Use equipment rated for cylinder pressure.

Use a backflow preventative device in piping.

Wash thoroughly after handling.

Close valve after each use and when empty.

Do not enter confined spaces unless adequately ventilated.

DO NOT CUT, DRILL, GRIND, OR WELD ON OR NEAR THIS CONTAINER.

Emptied container retains vapor and product residue.

Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.

Storage**General information on storage conditions:**

Keep away from direct sunlight. Keep cylinders restrained. Store in cool, dry, well ventilated area away from sources of ignition such as flame, sparks and static electricity.

Storage stability – Remarks:

Do not apply direct flame to cylinder. Do not store cylinder in direct sun or expose it to heat above 120 F (48.9 C.).

Do not drop or refill this cylinder.

Storage incompatibility – General:

Store separate from:

Finely divided metals (aluminium, magnesium, zinc...)

Strong bases

Alkali metals

Alkaline earth metals

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Ethane, 1,1,1,2-tetrafluoro- (811-97-2)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Time weighted average	1,000 ppm (4,240 mg/m3)
-----------------------	-------------------------

Remarks:	Listed
----------	--------

Ethane, pentafluoro- (354-33-6)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Time weighted average	1,000 ppm (4,900 mg/m3)
-----------------------	-------------------------

Remarks:	Listed
----------	--------

Methane, difluoro- (75-10-5)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Time weighted average	1,000 ppm (2,200 mg/m3)
-----------------------	-------------------------

Remarks:	Listed
----------	--------

Ethane, 1,1,1-trifluoro- (420-46-2)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Time weighted average	1,000 ppm (3,400 mg/m3)
-----------------------	-------------------------

Remarks:	Listed
----------	--------

Only those components with exposure limits are printed in this section. Limits with skin contact designation above have skin contact effect. Air sampling alone is insufficient to accurately quantitate exposure. Measures to prevent significant cutaneous absorption may be required. Limits with a sensitizer designation above mean that exposure to this material may cause allergic reactions.

Engineering controls:

Investigate engineering techniques to reduce exposures below airborne exposure limits or to otherwise reduce exposures. Provide ventilation if necessary to minimize exposures or to control exposure levels to below airborne exposure limits (if applicable see above). If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment.

Monitor carbon monoxide and oxygen levels in tanks and enclosed spaces. Consult ACGIH ventilation manual, NFPA Standard 91 and NFPA Standard 654 for design of exhaust system and safe handling.

Respiratory protection:

Avoid breathing gas. Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components (full facepiece recommended). Consult respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Skin protection:

Wear appropriate chemical resistant protective clothing and chemical resistant gloves to prevent skin contact. Consult glove manufacturer to determine appropriate type glove material for given application. Rinse immediately if skin is contaminated. Wash contaminated clothing and clean protective equipment before reuse. Wash thoroughly after handling.

Eye protection:

Use good industrial practice to avoid eye contact.

9. PHYSICAL AND CHEMICAL PROPERTIES
--

Color:	Clear - colourless
Physical state:	gaseous
Form:	Liquefied gas
Odor:	Ether-like (slightly)
Odor threshold:	not determined
Flash point	Not applicable
Auto-ignition temperature:	1,369 °F (743 °C)
Lower flammable limit (LFL):	None.

FORANE® 427A

Upper flammable limit (UFL):	None.
pH:	Not applicable
Density:	1.17 g/cm ³
Vapor pressure:	8,052 mmHg (68 °F (20 °C))
Vapor density:	not determined
Boiling point/boiling range:	-44.9 - -31.9 °F (-42.7 - -35.5 °C)
Melting point/range:	No data available
Freezing point:	No data available
Evaporation rate:	No data available
Solubility in water:	not determined
Viscosity, dynamic:	No data available
Oil/water partition coefficient:	Not applicable
Thermal decomposition	No data available
Flammability:	See GHS Classification in Section 2

10. STABILITY AND REACTIVITY**Stability:**

This material is chemically stable under normal and anticipated storage, handling and processing conditions.

Hazardous reactions:

None known.

Materials to avoid:

Alkaline earth metals
Strong oxidizing agents
Finely divided metals (aluminium, magnesium, zinc...)
Alkali metals
Strong bases

Conditions / hazards to avoid:

Heat

Hazardous decomposition products:

Thermal decomposition giving toxic and corrosive products :
Hydrogen fluoride
Carbonyl halides

Carbon oxides

11. TOXICOLOGICAL INFORMATION

Data on this material and/or its components are summarized below.

Data for Ethane, 1,1,1,2-tetrafluoro- (811-97-2)**Acute toxicity****Inhalation:**

Practically nontoxic. (Rat) 4 h LC50 approximately 567000 ppm.

Signs/effects reported after acute exposure (mouse, dog, cat, monkey) signs: anesthetic effects

Skin Irritation:

Practically non-irritating. (Rabbit) Irritation Index: < 1 / 8. (24 h) (occluded exposure)

Eye Irritation:

Causes mild eye irritation. (Rabbit) (vapor)

Sensitization:

Causes cardiac sensitization. inhalation. (Dog) Stress induced heart effects: irregular heart beat, rapid heart beat, in some cases, sudden death (Reaction may occur in response to stress (natural adrenaline release) or administration of epinephrine.)

Skin Sensitization:

Not a sensitizer. Guinea pig maximization test. No skin allergy was observed

Repeated dose toxicity

Chronic inhalation administration to Rat / No adverse systemic effects reported.

Carcinogenicity

Chronic inhalation administration to male rat / affected organ(s): testes / signs: tumors were benign., Increase in tumor incidence was reported.

Chronic inhalation administration to female rat / signs: No increase in tumor incidence was reported.

Chronic inhalation administration to Mouse / signs: No increase in tumor incidence was reported.

1 year oral gavage administration to Rat / signs: No increase in tumor incidence was reported.

Genotoxicity**Assessment in Vitro:**

No genetic changes were observed in laboratory tests using: bacteria, animal cells, yeast, human cells

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in laboratory tests using: rats, mice

FORANE® 427A

Developmental toxicity

Exposure during pregnancy. inhalation (Rat) / No birth defects were observed. (delays in development, at doses that produce effects in mothers)

Exposure during pregnancy. inhalation (Rabbit) / No birth defects were observed.

Reproductive effects

Two-generation study. inhalation (Rat) / No toxicity to reproduction.

Data for Ethane, pentafluoro- (354-33-6)**Acute toxicity****Inhalation:**

Practically nontoxic. (Rat) 4 h LC50 > 800000 ppm. (Gas)

Sensitization:

Causes cardiac sensitization. inhalation. (Dog) Stress induced heart effects: irregular heart beat, rapid heart beat, in some cases, sudden death (Reaction may occur in response to stress (natural adrenaline release) or administration of epinephrine.)

Repeated dose toxicity

Subchronic inhalation administration to Rat / No adverse systemic effects reported.

Genotoxicity**Assessment in Vitro:**

No genetic changes were observed in laboratory tests using: bacteria, animal cells, human cells

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in laboratory tests using: mice

Developmental toxicity

Exposure during pregnancy. inhalation (rat and rabbit) / No birth defects were observed.

Data for Methane, difluoro- (75-10-5)**Acute toxicity****Inhalation:**

Practically nontoxic. (Rat) 4 h LC50 > 520000 ppm. signs: anesthetic effects, central nervous system depression

Sensitization:

Cardiac sensitization not observed. inhalation. (Dog) tremors

Repeated dose toxicity

Subchronic inhalation administration to Rat / No adverse effects reported.

Genotoxicity**Assessment in Vitro:**

FORANE® 427A

No genetic changes were observed in laboratory tests using: bacteria, animal cells, human cells

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in a laboratory test using: mice

Developmental toxicity

Exposure during pregnancy. inhalation (rat and rabbit) / No birth defects were observed.

Data for Ethane, 1,1,1-trifluoro- (420-46-2)**Acute toxicity****Inhalation:**

No deaths occurred. (Rat) 4 h LC0 > 591000 ppm.

Sensitization:

Causes cardiac sensitization. Inhalation. (Dog) Stress induced heart effects: irregular heart beat, rapid heart beat, in some cases, sudden death (Reaction may occur in response to stress (natural adrenaline release) or administration of epinephrine.)

Repeated dose toxicity

Repeated inhalation administration to rat and guinea pig / affected organ(s): lung / signs: irritation, bronchitis, pneumonia

Chronic oral administration to rat / No adverse effects reported.

Carcinogenicity

Chronic oral administration to rat / signs: No increase in tumor incidence was reported.

Genotoxicity**Assessment in Vitro:**

No genetic changes were observed in laboratory tests using: bacteria, human cells

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in laboratory tests using: mice

Developmental toxicity

Exposure during pregnancy. Inhalation (rat and rabbit) / No birth defects were observed.

12. ECOLOGICAL INFORMATION**Chemical Fate and Pathway**

Data on this material and/or its components are summarized below.

Data for Ethane, 1,1,1,2-tetrafluoro- (811-97-2)**Biodegradation:**

Not readily biodegradable. (28 d) biodegradation 3 %

FORANE® 427A

Octanol Water Partition Coefficient:

log Pow = 1.06

Photodegradation:

Degradation in the atmosphere Half-life direct photolysis: 9.6 - 16.7 y

Global Warming Potential:

GWP 0.3 (Halocarbon global warming potential.)

GWP 1,320 (Global warming potential with respect to CO₂ (time horizon 100 years))**Ozone Depletion Potential:**

ODP 0

Data for Ethane, pentafluoro- (354-33-6)**Biodegradation:**

Not readily biodegradable. (Closed Bottle test, 28 d) biodegradation 5 %

Octanol Water Partition Coefficient:

log Pow = 1.48

Global Warming Potential:

GWP 0.84 (Halocarbon global warming potential; HGWP; (R-11 = 1))

GWP 3,450 (Global warming potential with respect to CO₂ (time horizon 100 years))**Ozone Depletion Potential:**

ODP 0.001 (Ozone depletion potential; ODP; (R-11 = 1))

Data for Methane, difluoro- (75-10-5)**Biodegradation:**

Not readily biodegradable. (28 d) biodegradation 5 %

Octanol Water Partition Coefficient:

log Pow = 0.21

Global Warming Potential:GWP 543 (Global warming potential with respect to CO₂ (time horizon 100 years))**Ozone Depletion Potential:**

ODP 0 (Ozone depletion potential; ODP; (R-11 = 1))

Data for Ethane, 1,1,1-trifluoro- (420-46-2)**Biodegradation:**

Not readily biodegradable. (28 d) biodegradation 3 - 10 % / similar material

Octanol Water Partition Coefficient:

log Pow = 1.73 (calculated)

Global Warming Potential:GWP 3,800 (Global warming potential with respect to CO₂ (time horizon 100 years))

FORANE® 427A**Ozone Depletion Potential:**

ODP 0 (Ozone depletion potential; ODP; (R-11 = 1))

Ecotoxicology

Data on this material and/or its components are summarized below.

Data for Ethane, 1,1,1,2-tetrafluoro- (811-97-2)**Aquatic toxicity data:**

Practically nontoxic. Oncorhynchus mykiss (rainbow trout) 96 h LC50 = 450 mg/l

Aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 = 930 mg/l

Microorganisms:

Practically nontoxic. Pseudomonas putida 16 h EC10 > 730 mg/l

Data for Ethane, 1,1,1-trifluoro- (420-46-2)**Aquatic toxicity data:**

No adverse effects reported. Oncorhynchus mykiss (rainbow trout) 96 h LC0 >= 175 mg/l (Nominal concentration)

Aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 = 300 mg/l

13. DISPOSAL CONSIDERATIONS**Waste disposal:**

Do not vent the container contents, or product residuals, to the atmosphere. Recover and reclaim unused contents or residuals as appropriate. Recovered/reclaimed product can be returned to an approved certified reclaimer or back to the seller depending on the material. Completely emptied disposable containers can be disposed of as recyclable steel. Returnable cylinders must be returned to seller. Dispose of in accordance with federal, state and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste disposal requirements may be more restrictive or otherwise different from federal laws and regulations.

14. TRANSPORT INFORMATION**US Department of Transportation (DOT)**

UN Number : 3163
Proper shipping name : Liquefied gas, n.o.s.
Technical name : (1,1,1,2-Tetrafluoroethane, Pentafluoroethane)
Class : 2.2
Marine pollutant : no

International Maritime Dangerous Goods Code (IMDG)

UN Number : 3163

Proper shipping name : LIQUEFIED GAS, N.O.S.
 Technical name : (1,1,1,2-TETRAFLUOROETHANE, PENTAFLUOROETHANE)
 Class : 2.2
 Marine pollutant : no

15. REGULATORY INFORMATION

Chemical Inventory Status

EU. EINECS	EINECS	Conforms to
United States TSCA Inventory	TSCA	The components of this product are all on the TSCA Inventory.
Canadian Domestic Substances List (DSL)	DSL	All components of this product are on the Canadian DSL
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Does not conform
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Conforms to
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Conforms to
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Conforms to
Australia Inventory of Chemical Substances (AICS)	AICS	Conforms to

United States – Federal Regulations

SARA Title III – Section 302 Extremely Hazardous Chemicals:

The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:

Acute Health Hazard, Sudden Release of Pressure Hazard

SARA Title III – Section 313 Toxic Chemicals:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):

The components in this product are either not CERCLA regulated, regulated but present in negligible concentrations, or regulated with no assigned reportable quantity.

FORANE® 427A

United States – State Regulations

New Jersey Right to Know

<u>Chemical Name</u>	<u>CAS-No.</u>
Ethane, 1,1,1-trifluoro-	420-46-2
Methane, difluoro-	75-10-5

New Jersey Right to Know – Special Health Hazard Substance(s)

<u>Chemical Name</u>	<u>CAS-No.</u>
Ethane, 1,1,1-trifluoro-	420-46-2

Pennsylvania Right to Know

<u>Chemical Name</u>	<u>CAS-No.</u>
Ethane, 1,1,1,2-tetrafluoro-	811-97-2
Ethane, pentafluoro-	354-33-6
Ethane, 1,1,1-trifluoro-	420-46-2
Methane, difluoro-	75-10-5

Pennsylvania Right to Know – Environmentally Hazardous Substance(s)

<u>Chemical Name</u>	<u>CAS-No.</u>
Methane, difluoro-	75-10-5

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive defects.

16. OTHER INFORMATION

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

H220	Extremely flammable gas.
H280	Contains gas under pressure; may explode if heated.

Latest Revision(s):

Revised Section(s):	Revision chapter 9 GHS
Reference number:	000000058715
Date of Revision:	10/17/2015
Date Printed:	10/21/2015

FORANE® is a registered trademark of Arkema Inc.

The statements, technical information and recommendations contained herein are believed to be accurate as of the date hereof. Since the conditions and methods of use of the product and of the information referred to herein are beyond our control, ARKEMA expressly disclaims any and all liability as to any results obtained or arising from any use of the product or reliance on such information; **NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY**

FORANE® 427A

OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE GOODS DESCRIBED OR THE INFORMATION PROVIDED HEREIN. The information provided herein relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. The user should thoroughly test any application before commercialization. Nothing contained herein constitutes a license to practice under any patent and it should not be construed as an inducement to infringe any patent and the user is advised to take appropriate steps to be sure that any proposed use of the product will not result in patent infringement. See SDS for Health & Safety Considerations.

Arkema has implemented a Medical Policy regarding the use of Arkema products in Medical Devices applications that are in contact with the body or circulating bodily fluids (<http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html>) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices, and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.

It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies) It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.