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® 409A
Synonyms: R-409A, HCFC 409A, FORANE FX 56
Molecular formula: Mixture
Chemical family: Hydrochlorofluorocarbon
Molecular weight: 97.43 g/mol
Product use: Refrigerant

2. HAZARDS IDENTIFICATION

Emergency Overview
Color: Clear - colourless
Physical state: gaseous
Form: Liquefied gas
Odor: Slightly ether-like

***Classification of the substance or mixture:**
Gases under pressure, Liquefied gas, H280
Hazardous to the ozone layer, Category 1, H420

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

GHS-Labelling

Hazard pictograms:

Signal word: **Warning**

Hazard statements:

H280 : Contains gas under pressure; may explode if heated.
H420 : Harms public health and the environment by destroying ozone in the upper atmosphere.

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.

Disposal:

P502 : Refer to manufacturer/ supplier for information on recovery/ recycling.

Supplemental information:

Potential Health Effects:

Liquid : Contact with liquid or refrigerated gas can cause cold burns and 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**
Methane, chlorodifluoro-	75-45-6	>= 60 - <= 100 %	H280, H420
Ethane, 2-chloro-1,1,1,2-tetrafluoro-	2837-89-0	>= 10 - < 30 %	H280, H420
Ethane, 1-chloro-1,1-difluoro-	75-68-3	>= 10 - < 30 %	H220, H280, H420, H412
Ethane, 1-chloro-1,1,2,2-tetrafluoro-	354-25-6	>= 1 - < 5 %	H280, H420

**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:
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:
Carbon oxides
Carbonyl halides
Hydrogen fluoride
hydrogen chloride

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.
Follow label warnings even after container is emptied.
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.
Improper disposal or reuse of this container may be dangerous and/or illegal.

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

Temperature tolerance – Do not store above:
118 °F (48 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Methane, chlorodifluoro- (75-45-6)

US. ACGIH Threshold Limit Values

Time weighted average	1,000 ppm

Ethane, 2-chloro-1,1,1,2-tetrafluoro- (2837-89-0)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Time weighted average	1,000 ppm
Remarks:	Listed

Ethane, 1-chloro-1,1-difluoro- (75-68-3)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Time weighted average	1,000 ppm (4,100 mg/m3)
Time weighted average	1,000 ppm (4,100 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 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:	Slightly ether-like
Odor threshold:	No data available
Flash point	Not applicable
Auto-ignition temperature:	not determined
Lower flammable limit (LFL):	None.
Upper flammable limit (UFL):	None.
pH:	Not applicable
Density:	not determined
Specific Gravity (Relative density):	1.21 (77 °F(25 °C))
Vapor pressure:	5,388 mmHg (70.0 °F (21.1 °C))
Vapor density:	3.38 kg/m3
Boiling point/boiling range:	-24 °F (-31 °C)
Melting point/range:	No data available.
Freezing point:	not determined
Evaporation rate:	No data available
Solubility in water:	negligible
Viscosity, dynamic:	No data available
% Volatiles:	100 %
Molecular weight:	97.43 g/mol

Oil/water partition coefficient:	No data available
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
Finely divided metals (aluminium, magnesium, zinc...)
Alkali metals
Strong bases
Strong oxidizing agents

Conditions / hazards to avoid:
Heat

Hazardous decomposition products:

Thermal decomposition giving toxic and corrosive products :
Hydrogen fluoride
hydrogen chloride
Carbonyl halides
Carbon oxides

11. TOXICOLOGICAL INFORMATION

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

Data for Methane, chlorodifluoro- (75-45-6)

Acute toxicity

Inhalation:
Practically nontoxic. (Rat) 4 h LC50 220000 ppm. (Gas)

Skin Irritation:
Practically non-irritating. (Rabbit) (Rapid evaporation of the liquid may cause frostbite.)

Eye Irritation:
Causes mild eye irritation. (Rabbit) (30 s) signs: Rapid evaporation of the liquid may cause frostbite (gas spray)

Sensitization:
Causes cardiac sensitization. (dog, rat, mouse, rabbit and monkey) 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. Repeated skin exposure. (Guinea pig) No skin allergy was observed

Repeated dose toxicity
Chronic inhalation administration to rat, mouse / No adverse systemic effects reported.

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

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

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

Chronic inhalation administration to male rat / affected organ(s): salivary gland / signs: Increased incidence of tumors was reported.

Genotoxicity

Assessment in Vitro:
Genetic changes were observed in laboratory tests using: bacteria

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

Genotoxicity

Assessment in Vivo:
No genetic changes were observed in laboratory tests using: mice

Developmental toxicity

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

Reproductive effects
Reproduction test. inhalation (rat and mouse) / No toxicity to reproduction / (males)

Human experience
Inhalation:
Lung: Asphyxia, suffocation.

Heart: Palpitation. (based on reports of occupational exposure to workers)

Human experience
Skin contact:
Skin: irritation, redness, swelling. (repeated or prolonged exposure)

Data for Ethane, 2-chloro-1,1,1,2-tetrafluoro- (2837-89-0)

Acute toxicity

Inhalation:
Practically nontoxic. (Rat) 4 h LC50 between 230000 - 300000 ppm. signs: anesthetic effects

Signs/effects reported after acute exposure (dog, mouse) anesthetic effects

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, mouse / affected organ(s): central nervous system / signs: blood chemistry changes

Carcinogenicity
Chronic inhalation 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, yeast, 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. (at doses that produce effects in mothers)

Reproductive effects
Repeated administration. inhalation (Rat) / Did not cause damage to the reproductive organs.

Data for Ethane, 1-chloro-1,1-difluoro- (75-68-3)

Acute toxicity

Inhalation:
Practically nontoxic. (rat) 6 h LC50 > 400000 ppm. signs: respiratory irritation (Gas)

Practically nontoxic. (rat) 4 h ALC ~ 128000 ppm. (Gas)

Eye Irritation:
Causes mild eye irritation. (rabbit) (liquid)

Sensitization:
Causes cardiac sensitization. Inhalation. (dog) 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 dog / No adverse systemic effects reported.

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

Genotoxicity

Assessment in Vitro:
Both positive and negative responses for genetic changes were observed in laboratory tests using: bacteria, animal cells

Genotoxicity

Assessment in Vivo:
No genetic changes were observed in laboratory tests using: rats

Developmental toxicity

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

Reproductive effects
Repeated administration. Inhalation (rat, dog) / Did not cause damage to the reproductive organs.
Exposure prior to mating. Inhalation (mouse) / No toxicity to reproduction. / (males)

Data for Ethane, 1-chloro-1,1,2,2-tetrafluoro- (354-25-6)

Acute toxicity

Inhalation:
Practically nontoxic. (Guinea pig) 2 h ALC > 200000 ppm. signs: anesthetic effects

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., (Results obtained on a similar product).)

Repeated dose toxicity
Repeated inhalation administration to Guinea pig / No adverse systemic effects reported.

12. ECOLOGICAL INFORMATION

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

Data for Methane, chlorodifluoro- (75-45-6)

Biodegradation:
Not readily biodegradable. (28 d) biodegradation 0 %

Octanol Water Partition Coefficient:
log Pow = 1.08 (Practically no potential to bioaccumulate.)

Photodegradation:
Half-life direct photolysis: = 8.4 y

Mobility and Distribution in the Environment:
Moderate adsorption / Log Koc = 1.8

Global Warming Potential:
GWP 1,810 (Global warming potential with respect to CO2 (time horizon 100 years))
GWP 0.33 (Halocarbon global warming potential; HGWP; (R-11 = 1))

Ozone Depletion Potential:
ODP 0.055 (Ozone depletion potential; ODP; (R-11 = 1))

Data for Ethane, 2-chloro-1,1,1,2-tetrafluoro- (2837-89-0)

Biodegradation:
Not readily biodegradable. (28 d) biodegradation 2 - 5 %

Octanol Water Partition Coefficient:
log Pow = 1.9 - 2.0

Global Warming Potential:
GWP 470 (Global warming potential with respect to CO2 (time horizon 100 years))

Ozone Depletion Potential:
ODP 0.02 (Ozone depletion potential; ODP; (R-11 = 1))

Data for Ethane, 1-chloro-1,1-difluoro- (75-68-3)

Biodegradation:
Not readily biodegradable. (20 d) biodegradation 5.60 %

Octanol Water Partition Coefficient:
log Pow = 1.64 - 2.05 (calculated)

Photodegradation:
Half-life direct photolysis: = 12.8 d

Global Warming Potential:
GWP 0.42 (Halocarbon global warming potential; HGWP; (R-11 = 1))
GWP 1,800 (Global warming potential with respect to CO2 (time horizon 100 years))

Ozone Depletion Potential:
ODP 0.065 (Ozone depletion potential; ODP; (R-11 = 1))

Data for Ethane, 1-chloro-1,1,2,2-tetrafluoro- (354-25-6)

Ozone Depletion Potential:
ODP 0.02

Ecotoxicology

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

Data for Methane, chlorodifluoro- (75-45-6)

Aquatic toxicity data:

Practically nontoxic. Brachydanio rerio (zebrafish) 96 h LC50 = 777 mg/l

Aquatic invertebrates:
Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 = 433 mg/l

Microorganisms:
Bacteria 24 h Toxicity threshold > 400 mg/l (under anaerobic conditions)

Data for Ethane, 1-chloro-1,1-difluoro- (75-68-3)

Aquatic toxicity data:
Practically nontoxic. Poecilia reticulata (guppy) 96 h LC50 = 220 mg/l

Aquatic invertebrates:
Practically nontoxic. Daphnia magna (Water flea) 48 h EC50 = 160 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	:	(Chlorodifluoromethane, 1-CHLORO-1,1-DIFLUOROETHANE)
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	:	(CHLORODIFLUOROMETHANE, 1-CHLORO-1,1-DIFLUOROETHANE)
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)	Conforms to
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Does not conform
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Does not conform
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Does not conform
Australia Inventory of Chemical Substances (AICS)	AICS	Does not conform

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:
The following components are subject to reporting levels established by SARA Title III, Section 313:

Chemical Name	CAS-No.	De minimis concentration	Reportable threshold:
Ethane, 1-chloro-1,1,2,2-tetrafluoro-	354-25-6	1.0 %	25000 lbs (Manufacturing and processing) 10000 lbs (Otherwise used (non-manufacturing/processing))
Methane, chlorodifluoro-	75-45-6	1.0 %	25000 lbs (Manufacturing and processing) 10000 lbs (Otherwise used (non-manufacturing/processing))
Ethane, 1-chloro-1,1-difluoro-	75-68-3	1.0 %	10000 lbs (Otherwise used (non-manufacturing/processing)) 25000 lbs (Manufacturing and processing)
Ethane, 2-chloro-1,1,1,2-tetrafluoro-	2837-89-0	1.0 %	25000 lbs (Manufacturing and processing) 10000 lbs (Otherwise used (non-manufacturing/processing))

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

Chemical Name	CAS-No.	Reportable quantity
Ethane, 1-chloro-1,1-difluoro-	75-68-3	100 lbs

Toxic Substances Control Act – Section 12(b):

Chemical Name	CAS-No.
Ethane, 1-chloro-1,1,2,2-tetrafluoro-	354-25-6

United States – State Regulations

New Jersey Right to Know

Chemical Name	CAS-No.
Methane, chlorodifluoro-	75-45-6
Ethane, 2-chloro-1,1,1,2-tetrafluoro-	2837-89-0
Ethane, 1-chloro-1,1-difluoro-	75-68-3
Ethane, 1-chloro-1,1,2,2-tetrafluoro-	354-25-6

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

Chemical Name	CAS-No.
Ethane, 1-chloro-1,1-difluoro-	75-68-3

Pennsylvania Right to Know

Chemical Name	CAS-No.
Methane, chlorodifluoro-	75-45-6
Ethane, 2-chloro-1,1,1,2-tetrafluoro-	2837-89-0
Ethane, 1-chloro-1,1-difluoro-	75-68-3

Pennsylvania Right to Know – Environmentally Hazardous Substance(s)

Chemical Name	CAS-No.
Methane, chlorodifluoro-	75-45-6

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.
H412 Harmful to aquatic life with long lasting effects.
H420 Harms public health and the environment by destroying ozone in the upper atmosphere.

Latest Revision(s):

Reference number:	000000057863
Date of Revision:	02/11/2016
Date Printed:	02/11/2016

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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.