

SPOTLEAK® 1039

1. PRODUCT AND COMPANY IDENTIFICATION

Company

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

Thio and Fine Chemicals

Customer Service Telephone Number: (800) 628-4453
(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: SPOTLEAK® 1039
Synonyms: Not available
Molecular formula: Mixture
Chemical family: mercaptans
Product use: Odour agents

2. HAZARDS IDENTIFICATION

Emergency Overview

Color: Colourless to yellow.
Physical state: liquid
Odor: stinging

*Classification of the substance or mixture:

Flammable liquids, Category 2, H225
Skin irritation, Category 2, H315
Eye irritation, Category 2A, H319
Skin sensitisation, Category 1, H317
Chronic aquatic toxicity, Category 2, H411

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

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GHS-Labeling

Hazard pictograms:



Signal word:

Danger

Hazard statements:

- H225 : Highly flammable liquid and vapour.
- H315 : Causes skin irritation.
- H317 : May cause an allergic skin reaction.
- H319 : Causes serious eye irritation.
- H411 : Toxic to aquatic life with long lasting effects.

Supplemental Hazard Statements:

- Objectionable odor may cause nausea, headache or dizziness.
- May displace oxygen and cause rapid suffocation.

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Precautionary statements:

Prevention:

- P210 : Keep away from heat, sparks, open flames, hot surfaces. No smoking.
- P233 : Keep container tightly closed.
- P240 : Ground/bond container and receiving equipment.
- P241 : Use explosion-proof electrical/ ventilating/ lighting equipment.
- P242 : Use only non-sparking tools.
- P243 : Take precautionary measures against static discharge.
- P261 : Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
- P264 : Wash skin thoroughly after handling.
- P272 : Contaminated work clothing should not be allowed out of the workplace.
- P273 : Avoid release to the environment.
- P280 : Wear protective gloves or eye protection or face protection.

Response:

- P303 + P361 + P353 : IF ON SKIN (or hair): Remove or take off immediately all contaminated clothing. Rinse skin with water and shower.
- P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P333 + P313 : If skin irritation or rash occurs: Get medical advice/ attention.
- P337 + P313 : If eye irritation persists: Get medical advice/ attention.
- P362 : Take off contaminated clothing and wash before reuse.
- P370 + P378 : In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.
- P391 : Collect spillage.

Storage:

- P403 + P235 : Store in a well-ventilated place. Keep cool.

Disposal:

- P501 : Dispose of contents or container to an approved waste disposal plant.

Supplemental information:

Potential Health Effects:

Objectionable odor may cause nausea, headache or dizziness.
 Gas/vapor is heavier than air and can cause suffocation by reducing oxygen available for breathing. May cause: coughing, increased breathing and heart rate, breathing difficulties, headache, nausea, cyanosis, rapid heart beat, loss of consciousness.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
2-Propanethiol, 2-methyl-	75-66-1	>= 30 - < 60 %	H225, H317, H411

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Thiophene, tetrahydro-	110-01-0	>= 30 - < 60 %	H225, H302, H315, H319, H412
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**For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1. Description of necessary 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:

In case of contact, immediately flush skin with soap and plenty of water. Get medical attention. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Ingestion:

If swallowed, DO NOT induce vomiting. Get medical attention. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms/effects, acute and delayed:

For most important symptoms and effects (acute and delayed), see Section 2 (Hazard Statements and Supplemental Information if applicable) and Section 11 (Toxicology Information) of this SDS.

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

Unless otherwise noted in Notes to Physician, no specific treatment noted; treat symptomatically.

5. FIREFIGHTING MEASURES

Extinguishing media (suitable):

Carbon dioxide (CO₂), Foam, Dry chemical

Extinguishing media (unsuitable):

High volume water jet

Water may be ineffective., Do not use a solid water stream as it may scatter and spread fire.

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).

SPOTLEAK® 1039**Further firefighting advice:**

Cool closed containers exposed to fire with water spray.
Do not use a solid water stream as it may scatter and spread fire.
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.
Do not allow run-off from fire fighting to enter drains or water courses.
Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:

Vapors are heavier than air and may travel along the ground or be moved by ventilation and ignited by heat, pilot lights, and other flames and ignition sources at locations distant from material handling point.
Vapours may form explosive mixture with air.
When burned, the following hazardous products of combustion can occur:
Carbon oxides
sulfur oxides
hydrogen sulfide
Hazardous organic compounds

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. Ventilate the area. Eliminate all ignition sources. Do not allow to enter drains or waterways. Avoid generation of vapors. Contain spill by building a dike using absorbent material. Absorb with non-combustible absorbent material (e.g. earth, diatomaceous earth) Sweep or scoop up using non-sparking tools and place into suitable properly labeled containers for prompt disposal. Neutralize odor with a non-hazardous neutralization agent. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. 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.

SPOTLEAK® 1039**7. HANDLING AND STORAGE****Handling****General information on handling:**

Avoid breathing vapor or mist.
Avoid contact with skin, eyes and clothing.
Keep away from heat, sparks and flames.
No smoking.
Keep container closed.
Use only with adequate ventilation.
Wash thoroughly after handling.
Check that all equipment is properly grounded and installed to satisfy electrical classification requirements.
Container hazardous when empty.
Follow label warnings even after container is emptied.
Do not enter confined spaces unless adequately ventilated.
RESIDUAL VAPORS MAY EXPLODE ON IGNITION.
DO NOT CUT, DRILL, GRIND, OR WELD ON OR NEAR THIS CONTAINER.
Improper disposal or reuse of this container may be dangerous and/or illegal.
Emptied container retains vapor and product residue.

Storage**General information on storage conditions:**

Keep in a dry, cool place. Keep away from direct sunlight. Keep container closed when not in use. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Store in well ventilated area away from heat and sources of ignition such as flame, sparks and static electricity. Ensure that all storage and handling equipment is properly grounded and installed to satisfy electrical classification requirements. Static electricity may accumulate when transferring material. All metal and groundable storage containers, including but not limited to drums, cylinders, Returnable Intermodal Bulk Containers (RIBCs) and Class C Flexible Intermodal Bulk Containers (FIBCs) must be bonded and grounded during filling and emptying operations. Observe all federal, state and local regulations and National Fire Protection Association (NFPA) Codes which pertain to the specific local conditions of storage and use, including OSHA 29 CFR 1910.106 and NFPA 30, 70, 77, and 497.

Storage incompatibility – General:

Store separate from: Strong oxidizing agents
Acids (concentrated solutions)
Alkali metals
Bases
Reducing agents
Hydrogen peroxide
Nitric acid
Hypochlorites

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Airborne Exposure Guidelines:****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

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sources of air contamination such as open process equipment.

Monitor carbon monoxide and oxygen levels in tanks and enclosed spaces. Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems.

Respiratory protection:

Avoid breathing vapor or mist. 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 equipment is recommended and, if used, replaces need for face shield and/or chemical goggles. 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. Wear chemical goggles, a face shield, and chemical resistant clothing such as a rubber apron when splashing may occur. Rinse immediately if skin is contaminated. Remove contaminated clothing immediately and wash before reuse. Clean protective equipment before reuse. Provide a safety shower at any location where skin contact can occur. Wash thoroughly after handling.

Eye protection:

Where eye contact may be likely, wear chemical goggles and have eye flushing equipment available.

9. PHYSICAL AND CHEMICAL PROPERTIES
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Color:	Colourless to yellow.
Physical state:	liquid
Odor:	stinging
Odor threshold:	approx. 0.1 ppb
Flash point	3 °F (-16 °C) (Tag closed cup)
Auto-ignition temperature:	455 °F (235 °C) (Method: Standard NF T 60 118)
Lower flammable limit (LFL):	1.1 %(V)
Upper flammable limit (UFL):	12.1 %(V)
pH:	not determined
Density:	896 kg/m3 (68 °F (20 °C))
Specific Gravity (Relative	0.896 (68 °F(20 °C))Water=1 (liquid)

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density):

Bulk density:	not determined
Vapor pressure:	59 mmHg (59 °F (15 °C)) calculated 89 mmHg (68 °F (20 °C))
Relative vapor density:	approximately 3.1 (Air = 1.0)
Vapor density:	No data available.
Boiling point/boiling range:	147 - 248 °F (64 - 120 °C)
Melting point/range:	< 32 °F (< 0 °C)
Freezing point:	< -51 °F (< -46 °C)
Evaporation rate:	Not applicable
Solubility in water:	insoluble
Solubility in other solvents: [qualitative and quantitative]	Soluble in: Hydrocarbons
Viscosity, dynamic:	0.835 mPa.s 68 °F (20 °C)
Oil/water partition coefficient:	(Not applicable)
Thermal decomposition:	842 °F (450 °C)
Flammability:	See GHS Classification in Section 2 if applicable

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:

- Reacts violently with :
Strong oxidizing agents
Acids (concentrated solutions)
Alkali metals
Bases
Reducing agents
Hydrogen peroxide
Nitric acid

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Hypochlorites

Conditions / hazards to avoid:

Keep away from heat and sources of ignition. To avoid thermal decomposition, do not overheat.

Hazardous decomposition products:

Thermal decomposition giving flammable and toxic products

Carbon oxides

sulfur oxides

hydrogen sulfide

Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

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

Data for SPOTLEAK® 1039**Acute toxicity****Oral:**

Acute toxicity estimate 2,683 mg/kg.

Dermal:

Acute toxicity estimate > 5,000 mg/kg.

Inhalation:

4 h Acute toxicity estimate > 40 mg/l. (vapor)

Data for 2-Propanethiol, 2-methyl- (75-66-1)**Acute toxicity****Oral:**

May be harmful if swallowed. (rat) LD50 = 4,729 mg/kg.

Dermal:

No deaths occurred. (rabbit) LD0 > 2,000 mg/kg.

Inhalation:

Practically nontoxic. (rat) 4 h LC50 = 98 mg/l. (vapor)

Skin Irritation:

Not irritating. (rabbit) Irritation Index: 0/8. (4 h) (occluded exposure)

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

May cause an allergic skin reaction. Buehler method. (guinea pig) Skin allergy was observed.

May cause allergic skin reaction. LLNA: Local Lymph Node Assay. (mouse) Skin allergy was observed.

SPOTLEAK® 1039**Repeated dose toxicity**

Subchronic oral, inhalation administration to rat / affected organ(s): kidney / signs: hyaline droplet nephropathy / (not considered relevant to humans)

Genotoxicity**Assessment in Vitro:**

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

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in laboratory tests using: mice

Developmental toxicity

Exposure during pregnancy. inhalation (rat and mouse) / No birth defects were observed.
Reproductive/Developmental Effects Screening Assay. oral (rat) / No birth defects were observed.

Reproductive effects

Reproductive/Developmental Effects Screening Assay. oral (rat) / No toxicity to reproduction.

Data for Thiophene, tetrahydro- (110-01-0)**Acute toxicity****Oral:**

Harmful if swallowed. (rat) LD50 = 1,850 mg/kg.

Dermal:

May be harmful in contact with skin. (rat) LD50 = 3,335 mg/kg.

Inhalation:

Practically nontoxic. (rat) 4 h LC50 = 22.6 mg/l. (vapor)

Skin Irritation:

Causes skin irritation. (rabbit) (4 h) (occluded exposure)

Eye Irritation:

Causes serious eye irritation. (rabbit)

Skin Sensitization:

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

Direct peptide reactivity assay (DPRA). Inconclusive.

KeratinoSens assay. Negative.

Human cell line activation test (h-CLAT). Positive.

Repeated dose toxicity

Subchronic inhalation administration to rat / signs: Local irritation / (vapor)

SPOTLEAK® 1039**Genotoxicity****Assessment in Vitro:**

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

Developmental toxicity

Exposure during pregnancy. Inhalation (rat) / No birth defects were observed. (at doses that produce effects in mothers)

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

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

Data for 2-Propanethiol, 2-methyl- (75-66-1)**Biodegradation:**

Not readily biodegradable. (63 d) biodegradation 6 %

Data for Thiophene, tetrahydro- (110-01-0)**Biodegradation:**

Not readily biodegradable. (28 d) biodegradation < 10 %

Octanol Water Partition Coefficient:

log Pow: = 1.8, at 68 °F (20 °C) pH = 7 (Method: calculated)

Ecotoxicology

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

Data for SPOTLEAK® 1039**Chronic toxicity to aquatic invertebrates:**

Practically nontoxic. Daphnia magna (Water flea) 21 d NOEC (reproduction) = 1.9 mg/l

Data for 2-Propanethiol, 2-methyl- (75-66-1)**Aquatic toxicity data:**

Harmful. Oncorhynchus mykiss (rainbow trout) 96 h LC50 = 34 mg/l

Aquatic invertebrates:

Toxic. Daphnia magna (Water flea) 48 h EC50 = 6.7 mg/l

Algae:

Harmful. Pseudokirchneriella subcapitata (green algae) 72 h EC50 = 24 mg/l

Chronic toxicity to aquatic plants:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 h NOEC = 6.41 mg/l

Data for Thiophene, tetrahydro- (110-01-0)**Aquatic toxicity data:**

Harmful. Danio rerio (zebra fish) 96 h LC50 > 24 mg/l

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Aquatic invertebrates:

Harmful. Daphnia magna (Water flea) 48 h EC50 = 24 mg/l

Algae:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 h ErC50 > 153.2 mg/l

Microorganisms:

Respiration inhibition / Activated sludge 3 h EC50 = 1,530 mg/l

Chronic toxicity to aquatic invertebrates:

Practically nontoxic. Daphnia magna (Water flea) 21 d NOEC (reproduction) = 1.9 mg/l

Chronic toxicity to aquatic plants:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 h NOEC (growth rate) 29.1 mg/l

13. DISPOSAL CONSIDERATIONS

Waste disposal:

Disposal via incineration is recommended. 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.

Take appropriate measures to prevent release to the environment.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number : 3336
 Proper shipping name : Mercaptans, liquid, flammable, n.o.s.
 Technical name : (tert-Butylmercaptan, Tetrahydrothiophene)
 Class : 3
 Packaging group : II
 Marine pollutant : yes

International Maritime Dangerous Goods Code (IMDG)

UN Number : 3336
 Proper shipping name : MERCAPTANS, LIQUID, FLAMMABLE, N.O.S.
 Technical name : (T-BUTYLMERCAPTAN, TETRAHYDROTHIOPHENE)
 Class : 3
 Packaging group : II
 Marine pollutant : yes
 Flash point : 3 °F (-16 °C) Tag closed cup

15. REGULATORY INFORMATION

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Chemical Inventory Status

US. Toxic Substances Control Act	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)	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, Fire 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):

<u>Chemical name</u>	<u>CAS-No.</u>	<u>Reportable quantity</u>
2-Propanethiol, 2-methyl-	75-66-1	100 lbs
Thiophene	110-02-1	100 lbs
Benzene	71-43-2	10 lbs

United States – State Regulations

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New Jersey Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
2-Propanethiol, 2-methyl-	75-66-1
Thiophene, tetrahydro-	110-01-0

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

<u>Chemical name</u>	<u>CAS-No.</u>
2-Propanethiol, 2-methyl-	75-66-1
Thiophene, tetrahydro-	110-01-0

Pennsylvania Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
2-Propanethiol, 2-methyl-	75-66-1
Thiophene, tetrahydro-	110-01-0
Carbon disulfide	75-15-0
Benzene, methyl-	108-88-3
Methanethiol	74-93-1
Furan, tetrahydro-	109-99-9
Benzene	71-43-2

Pennsylvania Right to Know – Environmentally Hazardous Substance(s)

<u>Chemical name</u>	<u>CAS-No.</u>
Carbon disulfide	75-15-0
Benzene, methyl-	108-88-3
Methanethiol	74-93-1
Furan, tetrahydro-	109-99-9

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Benzene 71-43-2

Pennsylvania Right to Know – Special Hazardous Substance(s)

<u>Chemical name</u>	<u>CAS-No.</u>
Benzene	71-43-2

California Prop. 65

WARNING! This product contains a chemical known to the State of California to cause cancer.

<u>Chemical name</u>	<u>CAS-No.</u>
Benzene	71-43-2

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

<u>Chemical name</u>	<u>CAS-No.</u>
Carbon disulfide	75-15-0

Benzene, methyl- 108-88-3

Benzene 71-43-2

16. OTHER INFORMATION

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

- H225 Highly flammable liquid and vapour.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.

Miscellaneous:

Other information: Refer to National Fire Protection Association (NFPA) Codes 30, 70, 77, and 497 and OSHA 29 CFR 1910.106, for safe handling.

Latest Revision(s):

Reference number: 200010559
 Date of Revision: 07/08/2019
 Date Printed: 07/09/2019

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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.