

### SPOTLEAK® 1007

### 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® 1007 Synonyms: Not available Molecular formula: Mixture Chemical family: mercaptans Product use: Odour agents

### 2. HAZARDS IDENTIFICATION

### **Emergency Overview**

colourless Color: Physical state: liquid

Odor: strong, stinging

\*Classification of the substance or mixture: Flammable liquids, Category 2, H225 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.

Product code: 001007 Version 5.0 Issued on: 07/09/2019 Page: 1 / 15



### **GHS-Labelling**

Hazard pictograms:







Signal word: Danger

### **Hazard statements:**

H225: Highly flammable liquid and vapour. H317: May cause an allergic skin reaction.

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.

#### **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.

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.

P333 + P313 : If skin irritation or rash occurs: Get medical advice/ attention.

P363: Wash contaminated clothing 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	>= 79 - <= 80 %	H225, H317, H411
Ethane, (methylthio)-	624-89-5	>= 19 - < 20 %	H225, H319, H412

<sup>\*\*</sup>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. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Thoroughly clean shoes before reuse.

#### Eyes:

Immediately flush eye(s) with plenty of water.

#### 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

#### 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:

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

#### 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.



### 7. HANDLING AND STORAGE

#### **Handling**

#### General information on handling:

Avoid breathing vapor or mist.

Avoid prolonged or repeated contact with skin.

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:** 



### **SPOTLEAK® 1007**

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 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

Color: colourless

Physical state: liquid

Odor: strong, stinging

Odor threshold: 0.1 ppb

Flash point < -15 °F (< -26 °C) (closed cup)

**Auto-ignition** 

temperature:

460 °F (238 °C)

Lower flammable limit

(LFL):

No data available.

Upper flammable limit

(UFL):

9.6 %(V) (for a component of this mixture)

pH: not determined





**Density:** 808 kg/m3 (68 °F (20 °C))

**Specific Gravity (Relative** 

density):

0.808 (68 °F( 20 °C))Water=1 (liquid)

Vapor pressure: 113 mmHg (59 °F (15 °C))(Method: calculated)

**Relative vapor density:** 3 (Air = 1.0)

Vapor density: No data available.

**Boiling point/boiling** 

range:

147 °F (64 °C)

Melting point/range: No data available.

Freezing point: No data available.

**Evaporation rate:** No data available

**Solubility in water:** 68 °F (20 °C) insoluble

Solubility in other

solvents: [qualitative and

quantative]

Soluble in: Hydrocarbons

Ethyl ether

Alcohol

Refractive index: 1.427 68 °F (20 °C)

Viscosity, dynamic: 0.546 mPa.s 68 °F (20 °C)

Oil/water partition

coefficient:

log Pow: 2.14(Pure substance)

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)



### **SPOTLEAK® 1007**

Alkali metals
Bases
Reducing agents
Hydrogen peroxide
Nitric acid
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® 1007

### **Acute toxicity**

#### Oral:

May be harmful if swallowed. (rat) LD50 = 5,000 mg/kg.

#### Dermal:

No deaths occurred. (rat) LD0 > 2.000 mg/kg.

#### Inhalation:

No deaths occurred. (rat) 1 h LC0 > 20 mg/l. (vapor)

#### Eye Irritation:

Causes mild eye irritation. (rabbit)

### 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)



### **SPOTLEAK® 1007**

### 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.

### 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 Ethane, (methylthio)- (624-89-5)

### **Acute toxicity**

### Oral:

Practically nontoxic. (rat) LD50 > 5,000 mg/kg.

#### Dermal:

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

### Inhalation:

Practically nontoxic. (rat) 4 h LC50 > 21.7 mg/l. (vapor)

#### Skin Irritation:

Causes mild skin irritation. (rabbit) (4 h)

#### Eye Irritation:

Causes serious eye irritation. (rabbit)

#### Skin Sensitization:

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

### Genotoxicity



#### Assessment in Vitro:

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

### 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 Ethane, (methylthio)- (624-89-5)

#### **Biodegradation:**

Not readily biodegradable. (28 d) biodegradation 41 %

### **Octanol Water Partition Coefficient:**

log Pow: = 1.54

#### Photodegradation:

air Half-life direct photolysis: estimated 1.9 d

### **Ecotoxicology**

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

### 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 Ethane, (methylthio)- (624-89-5)

#### Aquatic toxicity data:

Harmful. Danio rerio (zebra fish) 96 h LC0 > 49.8 mg/l

#### Aquatic invertebrates:

Harmful. Daphnia magna (Water flea) 48 h EC50 = 16 mg/l

#### Algae:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 h ErC50 > 500 mg/l

#### Microorganisms:





Respiration inhibition / Activated sludge 3 h EC50 > 1,000 mg/l

### Chronic toxicity to aquatic plants:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 d NOEC (growth rate) = 76 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, Methylethyl sulfide)

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, METHYL ETHYL SULPHIDE)

Class : 3 Packaging group : II Marine pollutant : yes

Flash point :  $< -15 \,^{\circ}\text{F} \, (< -26 \,^{\circ}\text{C}) \, \text{closed cup}$ 

### 15. REGULATORY INFORMATION

#### **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 IECSC

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

### <u>United States - Federal Regulations</u>

### 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> 2-Propanethiol, 2-methyl-	CAS-No. 75-66-1	Reportable quantity 100 lbs
Methane, thiobis-	75-18-3	100 lbs
Ethene	74-85-1	100 lbs

## <u>United States – State Regulations</u>

### **New Jersey Right to Know**

Chemical name	CAS-No.
2-Propanethiol, 2-methyl-	75-66-1





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

Chemical nameCAS-No.2-Propanethiol, 2-methyl-75-66-1

### Pennsylvania Right to Know

Chemical nameCAS-No.2-Propanethiol, 2-methyl-75-66-1

Ethane, (methylthio)- 624-89-5

Methane, thiobis- 75-18-3

Ethene 74-85-1

Methanethiol 74-93-1

Carbon disulfide 75-15-0

Methanol 67-56-1

Disulfide, dimethyl 624-92-0

### Pennsylvania Right to Know - Environmentally Hazardous Substance(s)

<u>Chemical name</u>	<u>CAS-No.</u>
Methane, thiobis-	75-18-3
Ethene	74-85-1
Methanethiol	74-93-1
Carbon disulfide	75-15-0
Methanol	67-56-1
Disulfide, dimethyl	624-92-0



### **SPOTLEAK® 1007**

California Prop. 65

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

 Chemical name
 CAS-No.

 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.

Chemical nameCAS-No.Carbon disulfide75-15-0

Methanol 67-56-1

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.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:
 200010556

 Date of Revision:
 07/09/2019

 Date Printed:
 07/09/2019

SPOTLEAK® 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 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.