

**LUPEROX® 101****1. PRODUCT AND COMPANY IDENTIFICATION****Company**

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

**Functional Additives**

**Customer Service Telephone Number:** (800) 331-7654  
(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:** LUPEROX® 101  
**Synonyms:** Not available  
**Molecular formula:** C<sub>16</sub> H<sub>34</sub> O<sub>4</sub>  
**Chemical family:** Organic peroxide - dialkyl peroxides  
**Product use:** initiator/catalyst

**2. HAZARDS IDENTIFICATION****Emergency Overview**

**Color:** yellow  
**Physical state:** liquid  
**Odor:** slightly, Bleach-like

**\*Classification of the substance or mixture:**

Flammable liquid., Category 4, H227  
Organic peroxides, Type C, H242  
Skin irritation, Category 2, H315

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

**GHS-Labeling**

Hazard pictograms:



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Signal word: **Danger**

**Hazard statements:**

H227 : Combustible liquid.  
 H242 : Heating may cause a fire.  
 H315 : Causes skin irritation.

**Supplemental Hazard Statements:**

Organic peroxide. Hazardous decomposition may occur.

**Precautionary statements:**

**Prevention:**

P210 : Keep away from heat/sparks/open flames/hot surfaces. No smoking.  
 P220 : Keep/Store away from clothing/ combustible materials.  
 P234 : Keep only in original container.  
 P264 : Wash skin thoroughly after handling.  
 P280 : Wear protective gloves/ eye protection/ face protection.

**Response:**

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.  
 P332 + P313 : If skin irritation occurs: 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.

**Storage:**

P410 : Protect from sunlight.  
 P411 + P235 : Maximum storage temperature is specified on label and in section 7 of SDS. Keep cool.  
 P420 : Store away from other materials.

**Disposal:**

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

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)	78-63-7	>= 92 - <= 96 %	H227, H242, H315
1,2-Dioxane, 3,3,6,6-tetramethyl-	22431-89-6	>= 2 - < 4 %	H242, H226, H335, H319, H315

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Pentene, 2,4,4-trimethyl-	25167-70-8	0.4499 %	H225, H304, H336, H400, H411
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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.

**Skin:**

In case of contact, immediately flush skin with plenty of water. Get medical attention. Remove contaminated clothing and shoes. 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) 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):**

Water spray, Foam, Dry chemical

**Extinguishing media (unsuitable):**

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).

**Further firefighting advice:**

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

Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.  
When burned, the following hazardous products of combustion can occur:  
Carbon oxides  
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. Avoid generation of vapors. Contain and collect spillage with non-combustible absorbent material such as sodium bicarbonate, sodium carbonate, calcium carbonate, clean sand or non-acidic clay and then wet down (dampen) the mixture with water. DO NOT USE peat moss. Sweep or scoop up using non-sparking tools and place into suitable properly labeled containers for prompt disposal. The sweepings should be wetted down further with water. 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:**

Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.  
Avoid contact with skin, eyes and clothing.  
Keep away from heat, sparks and flames.  
No smoking.  
Use only with adequate ventilation.  
Wash thoroughly after handling.  
Prevent product contamination.  
Keep container tightly closed and away from combustible materials.  
Keep only in the original container.  
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.  
RESIDUAL VAPORS MAY EXPLODE ON IGNITION.  
DO NOT CUT, DRILL, GRIND, OR WELD ON OR NEAR THIS CONTAINER.  
Do not reuse container as it may retain hazardous product residue.  
Improper disposal or reuse of this container may be dangerous and/or illegal.  
Emptied container retains vapor and product residue.

**LUPEROX® 101****Storage****General information on storage conditions:**

Keep container closed when not in use. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Outside or detached storage is preferred. 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. Store out of direct sunlight in a cool well-ventilated place. Store in original container. Store away from combustibles and materials to avoid. Refer also to National Fire Protection Association (NFPA) Code 400, Hazardous Materials Code. 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 stability – Remarks:**

Follow the recommended storage temperatures provided in this Section in order to maintain stability and oxygen content.

**Storage incompatibility – General:**

Store separate from:

Strong acids

Strong oxidizing agents

Reducing agents

Accelerators

Friedel - Crafts reaction catalyst

Brass

Copper

Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

**Temperature tolerance – Do not store below:–**

50 °F (10 °C)

**Temperature tolerance – Do not store above:**

100 °F (38 °C)

**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

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airborne exposure limits (if applicable see above). If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment.

Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems.

**Respiratory protection:**

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 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. Wash thoroughly after handling.

**Eye protection:**

Where there is potential for eye contact, wear chemical goggles and have eye flushing equipment immediately available.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>
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<b>Color:</b>	yellow
<b>Physical state:</b>	liquid
<b>Odor:</b>	slightly, Bleach-like
<b>Odor threshold:</b>	No data available
<b>Flash point</b>	160 °F (71 °C) (Setaflash closed cup)
<b>Auto-ignition temperature:</b>	No data available
<b>Lower flammable limit (LFL):</b>	No data available
<b>Upper flammable limit (UFL):</b>	No data available
<b>pH:</b>	No data available
<b>Density:</b>	0.87 g/cm <sup>3</sup> (77 °F (25 °C))
<b>Specific Gravity (Relative density):</b>	0.87 (77 °F (25 °C))Water=1 (liquid)

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<b>Vapor pressure:</b>	4.500 mmHg (104 °F (40 °C))
<b>Vapor density:</b>	No data available
<b>Boiling point/boiling range:</b>	Decomposes before boiling. Rate of decomposition increases with rising temperature.
<b>Melting point/range:</b>	46 °F (8 °C)
<b>Freezing point:</b>	46 °F (8 °C)sub-cools
<b>Evaporation rate:</b>	No data available
<b>Solubility in water:</b>	insoluble
<b>Viscosity, dynamic:</b>	No data available
<b>Oil/water partition coefficient:</b>	7.34 68 °F (20 °C) (Method: OECD Test Guideline 117)
<b>Self-Accelerating Decomposition Temperature (SADT):</b>	187 °F (86 °C) 30 pound container
<b>Thermal decomposition</b>	No data available
<b>Active oxygen content:</b>	10.25 - 10.47 %
<b>Flammability:</b>	See GHS Classification in Section 2

**10. STABILITY AND REACTIVITY**

**Stability:**

This material is chemically unstable and should only be handled under specified conditions. See HANDLING AND STORAGE section of this SDS for specified conditions.

**Hazardous reactions:**

Hazardous polymerization does not occur.

**Materials to avoid:**

- Strong acids
- Strong oxidizing agents
- Reducing agents
- Accelerators
- Friedel - Crafts reaction catalyst
- Brass
- Copper
- Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

**Conditions / hazards to avoid:**

See HANDLING AND STORAGE section of this SDS for specified conditions. SADT - Self Accelerating Decomposition Temperature. Lowest temperature at which the tested package size will undergo a self-accelerating decomposition reaction. This reaction will generate flammable vapors which may autoignite. The length of time to

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generate a decomposition reaction, after the SADT has been reached or exceeded, is dependent upon how much the SADT has been exceeded and the length of time needed for the reaction exotherm (heat spike from increasing decomposition rate) to initiate a rapid decomposition reaction. Typically, SADT is inversely proportional to package size. Larger packages will have a lower SADT due to smaller ratio to heat transfer area to volume of product.

**Hazardous decomposition products:**

Temperatures at or above SADT can result in the release of hazardous decomposition products which are flammable and may autoignite.

Thermal decomposition giving flammable and toxic products :

Carbon oxides

Hazardous organic compounds

**11. TOXICOLOGICAL INFORMATION**

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

**Data for LUPEROX® 101****Acute toxicity****Dermal:**

Acute toxicity estimate 4,316 mg/kg.

**Data for Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl) (78-63-7)****Acute toxicity****Oral:**

May be harmful if swallowed. (rat) LD<sub>0</sub> > 2,000 mg/kg.

**Dermal:**

May be harmful in contact with skin. (rabbit) LD<sub>50</sub> = 4,100 mg/kg.

**Skin Irritation:**

Causes skin irritation. (rabbit) Irritation Index: 2.3/8. (4 h)

**Eye Irritation:**

Causes mild eye irritation. (rabbit) Irritation Index: 1/110.

**Skin Sensitization:**

Not a sensitizer. Buehler Test. (guinea pig) No skin allergy was observed

**Repeated dose toxicity**

Repeated oral administration to rat / affected organ(s): liver, kidney / signs: changes in organ weights, changes in organ structure or function, hyaline droplet nephropathy

**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 a laboratory test using: mice

**Developmental toxicity**

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

**Data for 1,2-Dioxane, 3,3,6,6-tetramethyl- (22431-89-6)****Acute toxicity****Specific target organ toxicity - single exposure:**

May cause respiratory irritation.

**Skin Irritation:**

Causes skin irritation. (estimate based on composition)

**Eye Irritation:**

Causes serious eye irritation. (estimate based on composition)

**Other information**

The information presented is from representative materials in this chemical class. The results may vary depending on the test substance.

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

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

**Data for Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl) (78-63-7)****Stability in water:**

Half-life 2.7 h (@pH 4)

Half-life 2.7 h (@pH 7)

Half-life 2.8 h (@pH 9)

**Biodegradation:**

Not readily biodegradable. (60 d) biodegradation 0 %

**Octanol Water Partition Coefficient:**

log Pow = 7.34

**Data for Pentene, 2,4,4-trimethyl- (25167-70-8)****Biodegradation:**

Not readily biodegradable. (aerobic, 28 d) biodegradation 1.6 % / activated sludge

**Biological Oxygen Demand:**

Biochemical Oxygen Demand (BOD) = 0.19 mg/l

**LUPEROX® 101****Chemical Oxygen Demand:**

COD = 1.59 mg/g

**BOD/COD Ratio:**

BOD/COD = 0.12 %

**Bioaccumulation:**

BCF = 350 - 868 (Cyprinus carpio (Carp))

Moderate potential to bioaccumulate.

**Octanol Water Partition Coefficient:**

log Pow = 4.9

**Ecotoxicology**

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

**Data for Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl) (78-63-7)****Aquatic toxicity data:**No effect up to the limit of solubility. *Oryzias latipes* (Orange-red killifish) 96 h LC50 = 4.5 mg/l (nominal concentrations reported)**Algae:**No effect up to the limit of solubility. *Pseudokirchneriella subcapitata* 72 h EC50 > 0.236 mg/l (nominal concentrations reported)**Microorganisms:**

No effect up to the limit of solubility. Activated sludge 3 h NOEC (Respiration inhibition) &gt; 1,000 mg/l (nominal concentrations reported)

**Chronic toxicity to aquatic invertebrates:**No effect up to the limit of solubility. semi-static test / *Daphnia magna* (Water flea) 21 d LOEC > 0.0065 mg/l**Chronic toxicity to aquatic plants:**No effect up to the limit of solubility. static test / *Pseudokirchneriella subcapitata* 72 h NOEC > 0.236 mg/l**Data for Pentene, 2,4,4-trimethyl- (25167-70-8)****Aquatic toxicity data:**Very toxic. *Oncorhynchus mykiss* (rainbow trout) 96 h LC50 = 0.58 mg/l**Aquatic invertebrates:**Toxic. *Daphnia magna* (Water flea) 48 h EC50 = 1.2 mg/l**Algae:**Toxic. *Pseudokirchneriella subcapitata* (green algae) 72 h ErC50 = 1.5 mg/l**Microorganisms:**Practically nontoxic. *Pseudomonas fluorescens* 24 h EC0 > 1,000 mg/l**Chronic toxicity to aquatic invertebrates:***Daphnia magna* (Water flea) 21 d NOEC (Reproduction inhibition) = 0.16 mg/l

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**13. DISPOSAL CONSIDERATIONS**

**Waste disposal:**

Dilution followed by incineration is the preferred method. Dilution ratio of 10:1 in a clean, compatible, combustible solvent (i.e., Fuel Oil #2, mineral oil) will reduce reactivity hazard during incineration and transportation. 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 : 3103  
 Proper shipping name : Organic peroxide type C, liquid  
 Technical name : (2,5-Dimethyl-2,5-di(tert-butylperoxy) hexane, 90-100%)  
 Class : 5.2  
 Packaging group : II  
 Marine pollutant : no

**International Maritime Dangerous Goods Code (IMDG)**

UN Number : 3103  
 Proper shipping name : ORGANIC PEROXIDE TYPE C, LIQUID  
 Technical name : (2,5-DIMETHYL-2,5-DI(TERT-BUTYLPEROXY) HEXANE, 90-100%)  
 Class : 5.2  
 Packaging group : II  
 Marine pollutant : no  
 Flash point : 160 °F (71 °C) Setflash closed cup

**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

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Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Does not conform
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:**

Fire Hazard, Reactivity Hazard, Acute Health 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-Propanol, 2-methyl-	75-65-0	100 lbs
Peroxide, bis(1,1-dimethylethyl)	110-05-4	100 lbs

**United States – State Regulations**

**New Jersey Right to Know**

No components are subject to the New Jersey Right to Know Act.

**Pennsylvania Right to Know**

<u>Chemical name</u>	<u>CAS-No.</u>
Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)	78-63-7
1,2-Dioxane, 3,3,6,6-tetramethyl-	22431-89-6
2-Propanol, 2-methyl-	75-65-0

**Pennsylvania Right to Know – Environmentally Hazardous Substance(s)**

<u>Chemical name</u>	<u>CAS-No.</u>
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2-Propanol, 2-methyl-

75-65-0

**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.**

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H227	Combustible liquid.
H242	Heating may cause a fire.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H411	Toxic 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: 000000034071  
Date of Revision: 05/17/2016  
Date Printed: 05/23/2016

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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,*

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*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.*